Public consultation meeting

Directive 2010/63/EU
Article 10 Feasibility Study

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30th March 2017

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Content

- *Background and legal context*
- *Preliminary work*
  - *State of play in 2014*
  - *Meeting of stakeholders June 2016*
- *Draft findings*
- *Discussion and next steps*

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EU Policy - Recital 19

*"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....*

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EU Policy - Recital 19

*"... 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..."*

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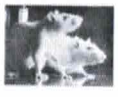
Progression



End use of wild caught animals

⇩

End use of F1s

⇩

Require only use of F2/F2+ generations

⇩

Self-sustaining colonies – use animals only those bred within the colony

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Exemption in Article 10(3)

*"Competent authorities **may grant exemptions** from paragraph 1 on the basis **of scientific justification**."*

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Article 10 and Annex II

From dates set out in Annex II, only allow the use of animals where they are offspring of non-human primates (NHPs) which have been bred in captivity or sourced from self-sustaining colonies

Species	Dates
Marmoset (Callithrix jacchus)	1 January 2013
Cynomolgus monkey (Macaca Mulatta)	5 years after publication of feasibility study*
Rhesus monkey (Macaca mulatta)	5 years after publication of feasibility study*
Other species of NHP	5 years after publication of feasibility study*
	* provided study does not recommend an extended period

Article 28

*"Member States shall 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**"*

- ***However, only applicable to breeders in the territory of EU***

Article 10 – feasibility study

- *COM to carry out a feasibility study on moving to second generation purposes bred NHPs*
- *Deadline 10 Nov 2017*
- *In consultation with MSs and stakeholders*
- *Propose amendments to Annex II where appropriate*

- ***No delegated powers:** any change to Annex II requires an amendment to the Directive*

Content

- *Background and legal context*
- *Preliminary work*
  - *State of play in 2014*
  - *Meeting of stakeholders June 2016*
- *Early findings*
- *Discussion and next steps*

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Non-Human Primate (NHP) Use in EU

	1999	2002	2005	2008	2011	2014 (draft)
Prosimians	450	1035	677	1201	83	140
New World	1383	1192	1564	904	700	417
Old World	5139	8075	8206	7404	5312	5642
Total	7007	10,360	10449	9569	6095	6229

NB – USA use in 2015 – 43,634 NHPs

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Origins of NHPs used in EU

	From EU	Other Origins	Total	% other origins
		Prosimians		
1999	325	124	450	27%
2002	1035	0	1035	0%
2005	677	0	677	0%
2008	1201	0	1201	0%
2011	83	0	83	0%
2014	140	0	140	0%
		New World Monkeys		
1999	1324	59	1383	4%
2002	1064	128	1192	11%
2005	1504	60	1564	4%
2008	904	0	904	0%
2011	649	51	700	7%
2014	411	6	417	1%
		Old World Monkeys		
1999	2403	2736	5139	53%
2002	1760	6315	8075	78%
2005	2016	5994	8210	73%
2008	4068	3336	7404	45%
2011	3522	1790	5312	34%
2014	553	5037	5590	90%

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New Statistical Reporting

Comm Implementing Decision (2012/707/EU amended by 2014/11/EU)

- Actual severity
- Genetically Altered Animals
- More detailed purposes
- Species of NHPs
- Source of NHPs
- Generation of NHPs (F0;F1;F2/F2+)

➢ Annual publication by MS since 2014

➢ EU report –triennial from 2019

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Non Human Primate Use 2014

Animal Species	Number of Animals
Prosimians	140
Marmoset and tamarins	417
Cynomolgus monkey	5,135
Rhesus monkey	348
Vervets Chlorocebus spp.	14
Baboons	183
Squirrel monkey	2
Other species of New World Monkeys (Ceboidea)	
Other species of Old World Monkeys (Cercopithecoidea)	
Other species of non-human primates	
Apes	
Total:	6,239

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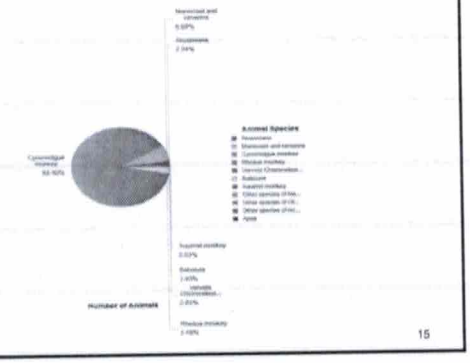
Non Human Primate Use 2014



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Non Human Primate Use 2014 by Member State

	BE	CZ	DE	ES	FR	HU	IT	NL	SE	UK	Total uses
Prosimians			85		55						140
Marmoset and tamarins			234				8	77		100	417
Cynomolgus monkey	8		1,475	382	547		443	18		2,382	5,185
Rhesus monkey	3		111	2	29	2	5	96		104	348
Vervets Chlorocebus spp.					14						14
Baboons			2	32	149						183
Squirrel monkey					2						2
Other species of New World Monkeys (Catarrhini)											
Other species of Old World Monkeys (Cercopithecoidea)											
Other species of non-human primates											
Total uses	11		1,907	416	792	2	454	191		2,486	6,239
%	0%		31%	7%	13%	0%	7%	3%		40%	

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Non Human Primate Use 2014 Origins

NHP Source (origin)	Number of uses	Percentage
Animals born at a registered breeder within EU	1,151	18.45%
Animals born in rest of Europe	57	0.91%
Animals born in Asia	1,936	31.01%
Animals born in America	14	0.22%
Animals born in Africa	3,081	49.38%
Animals born elsewhere	1	0.02%
Total uses	6,239	100.00%

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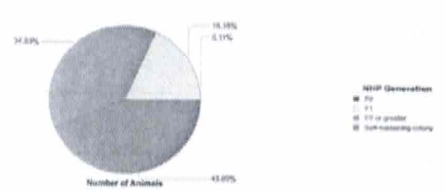
Non Human Primate Use 2014 Generation

NHP Source (origin)	Number of Animals
Animals born at a registered breeder within EU	1,151
Animals born in rest of Europe	57
Animals born in Asia	1,936
Animals born in America	14
Animals born in Africa	3,081
Animals born elsewhere	1
Total	6,239



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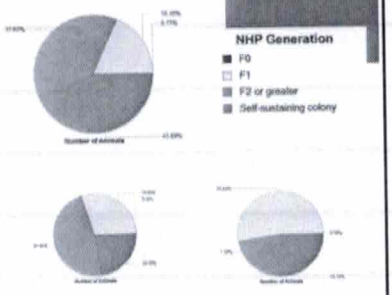
EU 2014

Generation of NHPs by MS

EU totals



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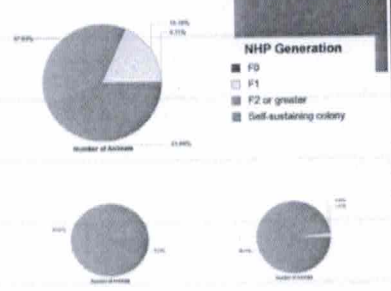
EU 2014

Generation of NHPs by MS

EU totals



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Species & Generation 2014

	F0	F1	F2 or greater	Self-sustaining colony	Total
Squirrel monkey				140	140
Cynomolgus monkey	6		101	312	419
Vervet / Green monkey	5	1,126	2,147	1,007	4,285
Rhesus monkey		4	94	335	433
Marmoset monkey			14		14
Baboon		6	2	179	187
Chimpanzee			2		2
Other species of New World monkeys in colonies					
Other species of Old World monkeys in colonies					
Other species of non-human primates					
Lemur					
Total	7	1,136	2,360	2,778	6,281

Only significant reporting of F1 use is for Cynomolgus monkey

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Source of cynomolgus 2014

NHP Source (origin)	Number of sites	Percentage
Animals born at a registered breeder within EU	237	98.34%
Animals born in rest of Europe	4	1.66%
Total sites	241	100.00%

NHP Generation	Number of sites	Percentage
F0		
F1		
F2 or greater	6	2.49%
Self-sustaining colony	235	97.51%
Total sites	241	100.00%

NHP Source (origin)	Number of sites	Percentage
Animals born in Asia	1,816	100.00%
Total sites	1,816	100.00%

NHP Source (origin)	Number of sites	Percentage
Animals born in Africa	3,675	100.00%
Total sites	3,675	100.00%

NHP Generation	Number of sites	Percentage
F0	2	0.11%
F1	25	1.38%
F2 or greater	1,622	89.32%
Self-sustaining colony	169	9.30%
Total sites	1,818	100.00%

NHP Generation	Number of sites	Percentage
F0	1	0.03%
F1	1,102	30.00%
F2 or greater	1,119	30.46%
Self-sustaining colony	1,453	47.25%
Total sites	3,675	100.00%

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- *Background and legal context*
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  - *Meeting of stakeholders June 2016*
- *Draft findings*
- *Discussion and next steps*

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Stakeholder meeting

- *MS in which NHPs are used*
  - **Authorities, users/breeders/suppliers**
- *Key stakeholder organisations (industry/academia)*
- *Specialised stakeholder organisations such as European Federation of Primatology*
- *NGOs for animal welfare*

➢ **Presentation of current state of play**
➢ **Discussion on study elements**

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Stakeholder meeting outcome

- Rhesus, Baboons, Prosimians, Vervets and Squirrel Monkeys already F2 *
- Concentrate on Cynomolgus
  - 22% F1
  - 40% F2
  - 37% Self – Sustaining Colony (SSC)

* *confirmed as F2 even from SSC*

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Stakeholder meeting outcome
Concerns to be addressed

- Demand and supply – in EU and from the 3rd countries
- Costs for F2/F2+
- Continued need for exemptions
- Health quality (incl Herpes B virus)
- Definition of Self-sustaining colony
- Animal welfare

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Stakeholder meeting outcome
Health quality

- Health quality
  - Herpes B virus
    - Europe is B virus free
    - Mauritius is B virus free
    - China
    - Vietnam

Herpes B
Human zoonotic infection

- Severe central nervous system disease
  - permanent neurological dysfunction
  - fatality rate (death) of approximately 80% if not treated
- Rare but associated with working with NHP
- Infection e.g. by splash in the eye, bites, scratches
- Proper personal protective equipment essential

Stakeholder meeting outcome

- Definition of self-sustaining colony
  - Differing interpretations
  - Could supply from SSC with F0 animals still in breeding colony
  - Follow-up enquiry to MS : 1 not able to obtain generation information without a change to 2012/707/EU
- Potential Animal Welfare concerns
  - Poor production of F1
  - Surplus male animals during transition

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Content

- *Background and legal context*
- *Preliminary work*
  - *Current state of play*
  - *Meeting of stakeholders*
- *Draft findings**
- *Discussion and next steps*

*Draft findings subject to change as the analysis continues

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Survey to users, breeders and suppliers of NHPs

- *Invitation to all users, breeders and suppliers of non-human primates (through MS)*
- *Requested contact details for overseas breeders and suppliers*
- *Responses from 35 EU users/breeders/suppliers*
- *Direct contact with overseas breeders/suppliers in Mauritius and Asia*

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EU Questionnaire on NHPs

➢ 36 responses from 8 MS

	Answers	Ratio
France	15	41.67 %
Germany	7	19.44 %
Spain	4	11.11 %
Netherlands	3	8.33 %
United Kingdom	3	8.33 %
Belgium	2	5.55 %
Italy	1	2.78 %
Sweden	1	2.78 %

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Are responses representative?

	BE	CZ	DE	ES	FR	HU	IT	NL	SE	UK	Total uses
Prosimians			55		55						140
Marmoset and tamarins			294				6	77		100	417
Cynomolgus monkey	6		1.475	282	647		443	18		2.262	5.135
Rhesus monkey	3		111	2	25	2	1	96		106	346
Vervets (Chlorocebus spp.)											14
Baboons					14						14
Squirrel monkeys			7	33	145						185
Other species of New World Monkeys (Platyrrhini)					2						2
Other species of Old World Monkeys (Catarrhini-monkey)											
Other species of non-human primates											
Total uses	11		1.957	418	768	2	464	191		2.468	6.238
%	0%		31%	7%	12%	0%	7%	3%		40%	

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Are responses representative?

	2014 Stats (4 species)	User responses for 2015				Total	Percentage of Total use
		Cynos	Marmos	Pigtailed m.	Galagos		
France	770	1000	21	10	10	1040	104%
Germany	1873	1800	120	50	4	1584	84%
Spain	210	37	8			42	20%
NL	114	28	103			131	114%
UK	1208	780	110			890	90%
Belgium	41		38			38	93%
Italy	448		5			5	1%
Sweden	0						0%
Hungary	0						0%

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EU Questionnaire on NHPs

1.4 The area(s) of activity of my organisation is(are)

	Answers	Ratio
Animal user in science or academia	24	66.67 %
Animal user in industry	10	27.78 %
Animal breeder	7	19.44 %
Animal supplier	5	13.89 %

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Species used by respondents

	Answers	Ratio
2.2.3 Cynomolgus (M fascicularis)	24	66.67 %
2.2.4 Rhesus (M mulatta)	18	50.00 %
2.2.5 Other New World NHPs	5	13.89 %
2.2.6 Baboons (Papio sp)	4	11.11 %
No Answer	3	8.33 %
2.2.1 Prosimians	2	5.56 %
2.2.5 Vervets (Chlorocebus sp)	1	2.78 %
2.2.6 Other Old World NHPs	1	2.78 %
2.2.2 Tamarins	0	0.00 %
2.2.7 Squirrel Monkeys	0	0.00 %

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2.1.4 Do you have any difficulties at present in sourcing suitable animals for your studies e.g. due to company/Member State policy on NHP sourcing, restrictions on the use of PIs or transport issues?

	Answers	Ratio
No	26	72.22 %
Yes	7	19.44 %
No Answer	3	8.33 %

Issues

- Transport – 5/7
- Correct scientific background e.g. aged animals; MHC classification – 2/7

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Establishment policy on use of F2 or higher generation for studies using NHPs

2.1.5 Do you have a policy on the use of F2 or higher generation for your studies?

	Answers	Ratio
No	19	52.78 %
Yes	14	38.89 %
No Answer	3	8.33 %

- Exemption from establishment considered if non-availability

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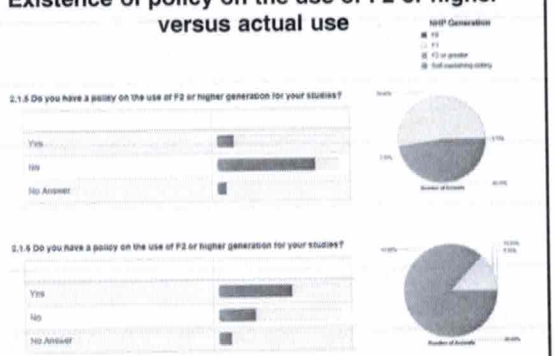
Existence of policy on the use of F2 or higher versus actual use



- EU policy adopted in 2010

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Obligation on suppliers to supply F2/F2+ NHPs

2.1.6 Do you have a policy in place requiring your suppliers to only supply F2/F2+?

	Answers	Ratio
No	17	47.22 %
Yes	16	44.44 %
No Answer	3	8.33 %

Why not?

- Shortage of F2s
- Not yet legal requirement

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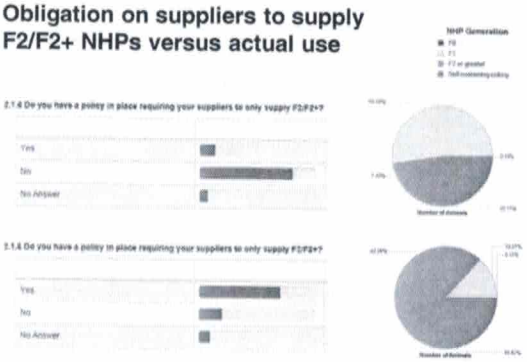
Obligation on suppliers to supply F2/F2+ NHPs versus actual use



- EU policy adopted in 2010

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Regulatory blocks on transition to F2/F2+ generation

2.1.7 Are there any regulatory demands that hinder the transition to F2/F2+?

	Answers	Ratio
No	32	88.89 %
No Answer	3	8.33 %
Yes	1	2.78 %

- Single reason for yes - "non-availability of animals"

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Checks by users on suppliers

- 90+% of users have checks in place
- Methods include
  - Individual health / production records
  - Colony health screening reports
  - Information from suppliers on accommodation and care practices
  - Audits by establishments
  - International Accreditation (AAALAC)

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Progress towards F2/F2+ use for individual species
Summary of key issues raised by users

- Transportation links
- Maintenance of sufficient gene pool / genetic diversity
- Retain possibility to request exemption to use F1 if no other suitable animal available
- Health status

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Responses from Overseas Suppliers Cynomolgus

- Direct responses from 2 Mauritian and 1 Asian supplier
- Information on further 6 Asian centres through EU Supplier

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Overseas breeders Cynomolgus

Supplied to EU				Total sales		
F0	F1	F2/+	T	F0	F1	F2/+
0	1510	2841	4359	28	3763	7855 by current EU suppliers Combined capacity: 13591 by all suppliers from where data received

F2 capacity by current EU suppliers significantly exceeds current use

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Overseas breeding centres

- Difficult to match supply and demand
- EU only part of global market
  - In 2015, USA used 32,962 NHPs ; USA imported 22,300 NHPs (90% Cynomolgus; 7% Rhesus)
- EU alone in legislating for F2
- Ethical issues re use of wild-caught in Mauritius

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Overseas breeding centres (3 responses)

- Breeding strategy to increase F2 animals
  - 1 response – already only supply F2/F2+
  - 2 responses
    - F1 parents – poorer reproductive performance and shorter breeding life than F0 generation
    - Surplus of F1 males during accelerated transition to F2 supply
    - Important to maintain genetic diversity

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Overseas breeding centres
Reproductive performance of F1 vs F0

- 2/3 – reduced numbers of births; higher pre-weaning MR; shortened breeding life
- 2/3 – health issues – obesity ; diabetes

versus

- 1/3 – improved reproductive performance and health (vs F0)
  - Considered due to improved nutrition/care practices in captive-bred colonies

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Feedback from EU NHP Breeders
Reproductive performance of F1 parents

- No differences noted between generations, but no comparison with F0 performance
- Good management practices deliver good results with naive breeding animals
  - Extended weaning to encourage natal skills
  - Mixed age breeding groups

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Surplus F1 Males

- Highlighted as a potential problem during transition
- In practice, this has been managed without unnecessary culling to date

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Animal Health

- Suitable health background necessary for good science
- Herpes B virus is zoonotic pathogen – risk to staff has to be managed
- Risks successfully managed by users in 7 MS who obtain Cynomolgus from Asian suppliers

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Cost of Cynomolgus F1 vs F2

- No significant price differences between F1 and F2 confirmed (concern raised at Commission Impact Assessment in 2007)
- One quoted the same price today for F2 as was stated in the Commission Impact Assessment – 10 years ago

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Availability of F2 animals

- Prosimians,Baboons,Vervets, Rhesus
- Good availability of F2/F2+ animals
- Special requirements re age; disease
- Health requirements

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Date by which F2 Cynomolgus available

2.2.3.10 By what date do you consider that there will be sufficient suitable F2/F2+ Cynomolgus (M fascicularis) to meet your needs?

	Answers	Ratio
Earlier than 2022	9	37.50 %
2022	6	25.00 %
2025	2	8.33 %
2026	5	20.83 %
Later than 2026	2	8.33 %

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Date by which F2 Cynomolgus available

- Users of 7/8 MS confirm feasibility of Annex II timelines – without negative impact on research
- Users of 1/8 MS
  - Those using >50% of animals in that MS confirm feasibility by 2022
  - The rest (in that MS) state additional years needed

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1 MS - User responses:

later than 2026	"I don't know"
later than 2026	"we don't know the **breeders capability to supply** our need if only F2 is required"
by 2024	"According to **discussion with supplier**"
by 2026	"Time would be needed for the **suppliers** to increase their stock and organize their work"
by 2026	"All F1 animals are used in research therefore **not available for breeding**. Accelerated switch would have major economic consequences for breeders"
by 2026	"Mostly due to **breeding capacity** and current population of F1 animals available for breeding (most of them are used in research), a long period of time shall be anticipated before 100% F2/F2+ animals are available, with an appropriate genetic diversity among this population." *(the same response by two different users)*
by 2026	"A sufficient number of animals might not be available before 2026 because of decreased fertility of F1 females and potential genetic diversity issue with F2 animals"
by 2026	"difficult to know, please see with breeders"

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Date by which F2 Cynomolgus available
EU and Overseas supplier responses:

- All EU breeders already supply only F2
- 2/3 of overseas breeders confirm by 2022 availability
- 1/3 overseas breeder F2 sufficiency achievable by 2023-2025 (instead of 2022)

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Date by which F2 Cynomolgus available

- Current F2 capacity of EU suppliers today exceeds total EU use
- Total world supply of F2 Cynomolgus exceeds EU needs for F2 (> 2.5 times)
- No significant price differences between F1 and F2 confirmed

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SSB

Other elements

- Legal Service views requested on
  - SSC definition
  - Use of exemption
- SSC – Comm Implementing Decision 2012/707/EU should be changed to require reporting of generation also when from SSC

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Slide 60

LSS8 I would say we keep the slide and I can answer. I've reminded LS on our meeting this week - have not heard back from them yet.

In any case, since this is a legal question, there's nothing much stakeholders can do. The COM will need to take account of the response and draw conclusions on these basis. No point in speculating what the outcome is.

LOUHIMIES Satu Susanna (ENV), 28/03/2017

Summary

- Rhesus already available as F2
- Other commonly used species (as per statistics) also available as F2
- Cynomolgus not yet fully available from all currently used suppliers as F2 – however, total supply exceeds demand

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Summary

- Continued need for exemption on scientific basis
- Definition of self-sustaining colony to be clarified
- Reporting to be changed to always include generation

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Next steps

- Finalise data analysis, further information on additional elements, where appropriate
- Present draft findings to MSs and stakeholders before April
- Policy decision to be incorporated in Art 58 Review report
- Review report adoption by 10 November 2017

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