AUT-F0476	FORM
VERSION 1	EFFECTIVE DATE 25 NOVEMBER 2014

EVALATUION RECORD FOR REVIEW OF RETROSPECTIVE ASSESSMENT

PROJECT AUTHORISATION NUMBER	
PROJECT TITLE	THE DETERMINATION OF POTENCY VALUE FOR BOTULINUM TOXIN PRODUCTS INCLUDING POTENCY TESTING ASSOCIATED WITH THE MANUFACTURE OF BOTULINUM TOXIN PRODUCTS
PROJECT MANAGER	

A. ANIMAL NUMBERS AND SEVERITY

1. Comment on whether the animal numbers differed from the original project authorisation and the reasons for this.

720,000 mice are authorised for use, however only 196,698 mice have been used to date under this project authorisation. Fewer animals have been used to date than anticipated as the number of animals required is determined by the number of samples that are submitted by the Client for testing, which is difficult to predict accurately.

2. What was the actual overall severity of the project and was this as predicted in the original project evaluation? If so, can you identify any reasons for this difference?

The actual severity to date has been:

- Severe for 85,519 animals
- Moderate for 26,190 animals
- Mild for 84,989 animals

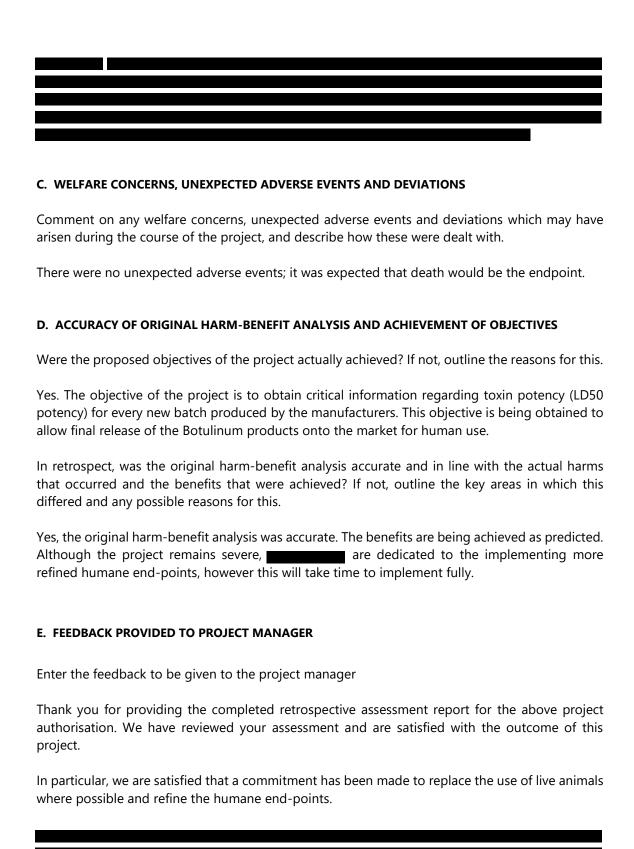
It was expected that a large proportion of the animals would experience severe suffering, therefore this is as predicted in the original project evaluation.

B. IMPLEMENTATION OF THE 3RS

Detail	any	elements	identified	that	may	contribute	to	the	further	implementation	of	the	3Rs
should	simi	lar work b	e conducte	ed in	futur	e.							

Although	have an	alternative	in	vitro	test	to	replace	the	LD50	testing	in	certain
circumstances, the i	remaining	Clients			C	lo n	ot. These	e Clie	ents are	e current	tly v	vorking
on developing and	validating	g an alternati	ive	but it	is no	t av	ailable a	s of y	et.			

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Please do not hesitate to contact us if you need any clarification on the content of this e-mail or the retrospective assessment process

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F. FEEDBACK FOR SCIENTIFIC ANIMAL PROTECTION ASSESSORS

Outline the key points of the feedback for scientific animal protection project assessors below.
This is a severe project, which includes death as an endpoint for LD50 testing of Botulinum toxin products. Although have an alternative in vitro test to replace the LD50 testing in certain circumstances, the remaining do not. These Clients are currently working on developing and validating an alternative but it is not available as of yet.
This project authorisation was renewed in and at the time the assessor included the following specific conditions:
1. Death as the end-point of the procedures in this authorisation shall be avoided and replaced by early and humane end-points.
2. The project manager must detailing the progress made in applying humane end-points on this project, including information on success rates with regards the identification of moribund animals for culling.
The project manager has recently submitted an update in relation to the implementation of humane endpoints (see correspondence from uploaded to have informed their Clients of their plan to conduct pilot studies to allow the implementation of
humane endpoints. The pilot studies will provide information on the time points at which the onset of the moribund status will be detected, allowing humane intervention to prevent further pain and suffering, without impacting on the performance of the assay. All Clients have agreed to this approach. It is planned to conduct the first study by
this approach, it is plainted to conduct the hist study by

G. KEY FINDINGS FOR THE NATIONAL COMMITTEE

Outline the key findings from this retrospective assessment which can be provided in the future to the National Committee if required.

This is a regulatory project involving Botulinum toxins and LD50 testing. Humane endpoints are being introduced for a procedure that to date has required death as an endpoint. This will involve increasing the monitoring of the animals to humanely euthanise the animals prior to death. In addition, one client has developed an alternative in vitro test to replace the LD50 testing in certain circumstances. However the remaining clients have not yet been able to replace LD50 testing with an alternative.

ASSESSOR SIGNATURE:

DATE: 09/03/16

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