



NATIONAL BIOSAFETY AUTHORITY

NACOSTI BUILDING (2ND FLOOR)
UPPER KABETE, OFF WAIYAKI WAY

P.O. Box 28251 – 00100, Nairobi. | **Tel:** +254 20 267 8667

Email: info@biosafetykenya.go.ke | **Website:** www.biosafetykenya.go.ke

Genome Edited Animal Decisions in Kenya

Anne Muia, BRED

Sixth International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies

Ghent, Belgium

November 6-7, 2025

Guidelines for Genome Editing in Kenya

- Published Feb. 2022; Revised Jan. 2025
- Apply to all genome edited organisms, across purposes
- Allows for **early consultation**:
 - Simplified application form to provide information/data to facilitate determination of regulatory pathway
- Determination of the regulatory pathway is based on:
 - Insertion of foreign genetic material
 - Whether the genome edit leads to:
 - new hazard
 - compositional (nutritional) alteration
 - other safety concern in the genome edited organisms or products
 - Intended use

Data Requirements

- Nature & identity of the organism
- Trait introduced
- Type of application
 - Research or Commercial Release
- Summary of molecular techniques used
- Genes edited plus outcome, with supporting data
 - deletion, insertion, substitution, replacement, chromosomal rearrangements
- Description of affected functions/ pathways as applicable

Data Requirements

- Description of techniques used to remove foreign genetic sequences
- Description of protocols used to confirm absence of inserted DNA sequences, e.g.
 - PCR - overlapping sequences of vector
 - Southern blot with multiple probes on multiple generations targeted to the transgenic cassette and vector backbone
 - Southern-by- Sequencing
 - WGS

.....*with supporting data*

- Intended use
- History of safe use if any

Application Submission



Fee

- Sh.170,000
(\$1300)
- Sh.850,000
(\$6500)

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APPLICATION FOR EARLY CONSULTATION ON GENOME EDITING TECHNOLOGY IN KENYA

This form will guide in determining whether genome editing organisms or their derived products are regulated under the Biosafety Act, 2009 or not.

SECTION I: APPLICANT INFORMATION

1.1 Name of Applicant, Address, Email, Telephone

ECT-QDU5D Early consultation on Genome Editing Technology in Kenya

STAGE RECORD REVIEW

Submitted Sep 29 12:09 pm

Payments

Receipt
KES.
850050.00
03 Oct,
2025

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Applicant	NBA (review within 90 days)	Relevant Regulatory Agency
<p>Submission of an Early Consultation Application to NBA in the prescribed format</p> <p>Communication of the Decision to the Applicant</p>	<p>Administrative Screening</p> <p>Technical Screening: integration of foreign DNA; new hazards</p> <p>ITC Review and Recommendation</p> <p>CEO's Decision</p> <p>Board's Decision</p> <p>Monitoring</p>	<p>Notification to the relevant regulatory agencies</p>



Review Process

ix. What functions and/ or pathways have been affected by the genome edit? **Specify**

NONE

No additional pathways have been affected by the genome editing.

There are six different SLICK alleles currently identified in different breeds of the Caribbean basin (SLICK1, 2, 3, 4, 5 and 6) all consist of 1 base pair (bp) mutations on exon 11 of PRLR that introduce premature stop codons, which truncate the encoded Prolactin Receptor protein. These alleles are associated with a morphological coat change with short, thin, and less dense hair and larger sweat glands known as the SLICK phenotype. These changes confer increased thermic resistance, consequently reducing heat stress effects, expressed as lower cortisol levels, which reflects in increased animal well-being and improved productive and reproductive performance under tropical conditions.

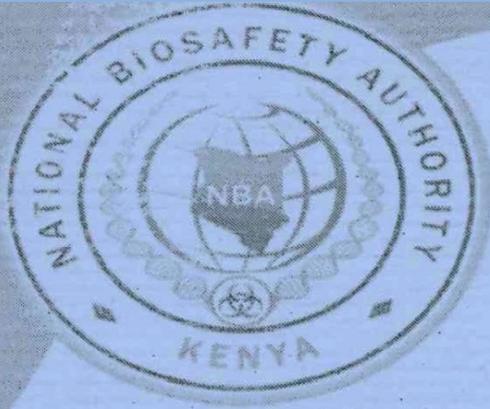
The two animals presented in this application, the “Slick edited Holstein” bulls DIEGO and DURANGO possess two copies of the allele equivalent to SLICK6

Review Process

xii. Is the foreign genetic material present in the end-product?	NO	There is no insertion of foreign genetic material into the genome of the animals.
xiii. Has the applicant sufficiently demonstrated how the foreign genetic materials were removed?	N/A	There is no insertion of foreign genetic material into the genome of the animals.
xiv. For processed products, is the foreign genetic material detectable?	N/A	There is no insertion of foreign genetic material into the genome of the animals.

- ITC Review
 - Recommends Decision
 - Recommends approval conditions
- 

Decision Making



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When replying please quote:
Our Ref: NBA/GMO/C09/123

30th October, 2025

**DECISION ON EARLY CONSULTATION ON THE INTRODUCTION OF
"SLICK EDITED HOLSTEIN" ANIMALS, DURANGO SD025-C1 AND DIEGO
SD009-C1 IN KENYA**

Decision Making

Following a review of the application, the Authority confirms that the gene-edited "**SLICK edited Holstein**" Bulls **DIEGO SD009-C1 and DURANGO SD025-C1**, and their semen do not contain foreign genetic material and do not therefore fall under the category of GMOs. The Authority thus has no objection to the proposed importation of semen to be used in the production of purebred Holstein and crossbred offspring in Kenya to be evaluated for milk production traits, fitness, survival and adaptation in challenging tropical environments.

- Approval is for five years, can be renewed
- Annual Reporting
- Independent monitoring by NBA

Conclusion

- No prescriptive data requirements pertaining to:
 - Techniques used to remove inserted foreign DNA sequence
 - Methods used to confirm absence of inserted foreign DNA sequence

→ *But must meet regulatory objectives*
 - For quick decision making, provide all required information in a clear & understandable manner
 - *Too much data is rarely the solution*
 - While off-targets do present some concern, we've not put any data requirement for this
 - *But it's better to not have them*
- ➔ Negotiations are accepted



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THANK YOU

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