Meat FSA Tool vs2

This FSA tool is for establishments that produce RAW MEAT PRODUCTS that are considered to fall under the following HACCP processing categories:

MEAT SLAUGHTER
INTACT MEAT
NON-INTACT MEAT

The FSA Tool contains the following main sections:

- **Hazard Analysis and HACCP System (Questions M1 – M23)**
- **Slaughter and Sanitary Dressing (M24 -M48)**
- **Outside Source Materials for Further Processing (M49 – M60)**
- **Antimicrobial Treatment for Slaughter and Further Processing (M61 – M67)**
- **Sampling and Testing for Slaughter and Further Processing (M68 – M89)**

In responding to questions in this tool, the EIAO is to focus on documenting any vulnerability and noncompliance, not making positive editorial findings.

A vulnerability is an identified weakness in the establishment's process that does not rise to the level of noncompliance but that could contribute to the establishment's ability to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR).

***References:**

1. **FSIS Directive 5100.1**, ***Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology***
2. **FSIS Directive 5000.2**, ***Review of Establishment Data by Inspection Personnel.***
3. ***Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-producing Escherichia coli (STEC) Organisms or Virulence Markers;***
4. ***FSIS Compliance Guideline for Controlling Salmonella in Market Hogs***

NOTE: For all questions in this FSA tool, please note that some FSA tool questions are not required questions and will only appear based on the answer responses provided. Also, it is not necessary to copy and paste information into a text field that you've provided in a previous text field question within the tool.

Hazard Analysis and HACCP System (Questions M1 – M23)

This section is designed to assess the establishment's HACCP system. The HACCP system includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

The EIAO is to document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.

NOTE: If there are findings specific to the antimicrobial treatments, sampling and testing, or sanitary dressing, briefly reference and provide more details in their respective sections of this tool.

M1 **Has the establishment considered relevant food safety hazards throughout the HACCP system?**

☐Yes

☐No

M2 **Briefly describe the hazard(s) not considered or identified. Also describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

M3 **Does the HACCP system include a prerequisite program/supporting documentation for any hazard that the establishment determines is not reasonably likely to occur?**

***Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If there are no such findings, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

M4 **Does each prerequisite program and/or supporting document support the decisions made?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M5 **Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur"?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M6 **Does the establishment utilize normal consumer-cooking practices to support hazard analysis decision-making?**

☐Yes - If selected, answer the following questions M7

☐No

M7 **Does the establishment have adequate support for the decisions made?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M8 **Considering all source materials used (i.e., self-supply through slaughter and outside source materials) and products produced (i.e., non-intact beef and non-intact beef components), does the establishment have measures in place to support that STEC has been reduced to below detectable levels and is a hazard "not reasonably likely to occur?"**
***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

M9 **Based on the measures applied, does the establishment conduct ongoing verification to**

demonstrate the measures continue to be effective and function as intended?
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M10 **Briefly describe the systematic approached used by the establishment to support STEC is "not reasonably likely to occur." Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

Click here to enter text.

M11 **Does the establishment maintain credible scientific or technical support for initial validation? (1st part – design)**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M12 **Does the establishment maintain in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome? (2nd part – execution)**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M13 **Does the establishment incorporate all critical operating parameters outlined in the validation documentation?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M14 **Does the establishment maintain support for the selected monitoring and verification procedures and frequencies?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M15 **If applicable, describe additional HACCP design findings not described in the previous questions and how you findings impact the establishment's food safety system.**

Click here to enter text.

M16 **Does the establishment conduct the CCP monitoring and verification (procedure and frequency) as written?**

☐Yes

☐No

M17 **Has the establishment had a deviation in the previous 60 days?**

NOTE: Answer this question based on your review of selected of records (including any additional record

review because of a food safety concern) as outlined in FSIS Directive 5100.1.

☐Yes - If selected, answer the following questions M18

☐No

M18 **Did the corrective actions meet the requirements of 417.3?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M19 **Does the HACCP plan set out a recordkeeping system that document monitoring, corrective action, verification (including on-going verification) and pre-shipment review the HACCP System?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M20 **Do the records include the actual times, temperatures, or other quantifiable values, and include the product code(s), product name or identity, or slaughter production lot?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M21 **Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product changes but the establishment did not reassess?**

☐Yes - If selected, answer the following questions M22

☐No

M22 **Was the hazard analysis and/or HACCP plan reassessed? If the reassessment showed that the HACCP plan or hazard analysis needed changes to meet regulatory requirements, was the HACCP plan or hazard analysis modified immediately?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

M23 **Briefly describe any vulnerability and any noncompliance concerning HACCP design or implementation that was not mentioned in a previous answer. Describe the impact your findings have on the food safety system.**

Click here to enter text.

Slaughter and Sanitary Dressing (M24 -M49)

This section is designed to assess the sanitary dressing and process controls slaughter establishments employ in its food safety systems, considering the factors and questions presented in

FSIS Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age - Revision 1*.

NOTE: The EIAO is to document all relevant noncompliance and vulnerability findings.

M24 **Does the establishment conduct slaughter activities?**

☐Yes - If selected, answer the following questions M25,M26,M27,M28,M29,M30,M31,M32,M33,M34,M35,M36,M37,38,M39,M40,M41,M42,M43,M44,M45 M46,M47,M48

☐No

M25 **Are there deficiencies in the slaughter floor design, production process, and equipment used, that could potentially result in carcass contamination?**

☐Yes

☐No

M26 **Does the establishment have written job descriptions and/or specific sanitation procedures that address sanitary dressing?**

☐Yes

☐No

M27 **Do employees receive training on the sanitary dressing procedures?**

☐Yes

☐No

M28 **Does the establishment monitor the sanitary dressing procedures?**

☐Yes

☐No

M29 **Briefly describe any vulnerability or noncompliance with the establishment's written sanitary dressing procedures, how the employees are trained, and how the monitoring is designed (employee technique audits, carcass audits, etc.) to show sanitary conditions are maintained. In the absence of sanitary dressing procedures, describe how the establishment ensures sanitary dressing is achieved.**

Click here to enter text.

M30 **Does the establishment monitor the overall effectiveness of the sanitary dressing procedures?**

☐Yes

☐No

M31 **Does the establishment use sanitary dressing standards or process control criteria to identify when the sanitary dressing procedures are not effective?**

☐Yes

☐No

M32 **Based on your review of the FSIS and establishment findings, have there been multiple or recurring sanitary dressing failures?**

☐Yes

☐No

M33 **Briefly describe your observation of the implemented sanitary dressing procedures, the effectiveness of the procedures/techniques, and the associated results generated. Include any reoccurring sanitary dressing failures over the previous 60 days, and evaluate the corrective actions taken. Briefly describe any vulnerability or noncompliance and the impact your findings have on the food safety system.**

NOTE: Answer this question based on your review of selected of records (including any additional record

review because of a food safety concern) according to FSIS Directive 5100.1.

Click here to enter text.

M34 **Does the establishment have written generic E. coli procedures?**

☐Yes

☐No

M35 **Does the establishment have support for the sampling method (excision/sponging) and sampling frequency (regulatory/alternative)?**

☐Yes

☐No

M36 **Over the past 60 days, has the establishment routinely met their process control limits?**

NOTE: Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1,

☐Yes

☐No

M37 **Briefly assess the sample collection and testing methodologies, observation of the implemented procedures, process control criteria, and any instances where the process control limits were exceeded. Briefly describe any vulnerability or noncompliance and the impact your findings have on the food safety system.**

Click here to enter text.

M38 **Does the establishment maintain support for the carcass chilling parameters?**

☐Yes

☐No

M39 **Does the establishment maintain documentation showing the implemented chilling process is consistently capable of meeting the chilling parameters for all carcasses?**

☐Yes

☐No

M40 **Briefly describe any vulnerability or noncompliance and assess the impact your findings have on the establishment's food safety.**

Click here to enter text.

Instructions: **Specified Risk Materials (SRMs)**

M41 **Does the establishment slaughter cattle or process carcasses/parts containing SRMs?**

***SRMs include: the tonsils and distal ileum of all cattle; the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia of cattle ≥30 months of age.**

☐Yes

☐No

M42 **Has the establishment developed, implemented, and maintained written procedures for the removal, segregation, and disposition of all SRMs?**

☐Yes

☐No

☐No, the establishment does not slaughter or process cattle containing SRMs.

M43 **Briefly describe the vulnerabilities and noncompliance concerning the written program, effectiveness of the implemented procedures and sanitation measures, and include any tracking controls in place. Summarize any associated NRs or inadequate corrective actions in the past 60 days. Assess the impact your findings have on the food safety system.**

NOTE: Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

Click here to enter text.

M44 **Does the establishment slaughter a class of animals associated with a higher rate of antibiotic residues (veal calves, cull cattle, show cattle, etc.)?**

☐Yes

☐No

M45 **Does the establishment consider drug and biological residues a hazard likely to occur, and address drug and biological residues with a CCP in the HACCP plan?**

☐Yes

☐No, the establishment has a pre-requisite program to prevent drug and biological residues and/or supporting documentation for why the drug and biological residues are not reasonably likely to occur

☐No, the hazard is not addressed

M46 **Is the establishment reviewing the "Repeat Violators Alert List" (posted on the USDA website at: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry) as part of their hazard analysis decision-making?**

☐Yes

☐No

M47 **Has the establishment received a "violative" tissue sample result from FSIS testing in the last 6 months?**

☐Yes

☐No

M48 **Describe any vulnerability s and noncompliance regarding any control(s) in place and establishment documentation available to address animal drugs and biological residues. Assess the impact your findings have on food safety.**

Click here to enter text.

Instructions: **Outside Source Materials for Further Processing (M49 – M60)**

M49 **Does the establishment use beef from outside sources (materials other than those slaughtered onsite)?**

☐Yes - If selected, answer the following questions M50,M51,M52

☐No

M50 **Does the establishment know the intended use of the products they receive?**

☐Yes

☐No

M51 **Does the establishment follow the designated intended use?**

☐Yes

☐No

M52 **Briefly describe the incoming source received and the intended use of the source materials. Document any instances where the product is not used in accordance with the intended use, and how the establishment addresses STEC on those products. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

M53 **Does the establishment provide buyers with information about STEC processing controls?**

☐Yes

☐No

M54 **Does the establishment provide buyers with sampling information and COAs?**

☐Yes

☐No

M55 **Does the establishment have a designated "intended use" for the products produced (i.e., intact product remains intact)?**

☐Yes - If selected, answer the following questions M57

☐No

M56 **Does the establishment communicate the "intended use" of the products to the receiving establishment or facility?**

☐Yes

☐No

M57 **Does the establishment produce not ready-to-eat (NRTE) non-intact product that receives a heat treatment but is not fully cooked (e.g., char-marked heat-treated but not fully cooked beef patties, chicken-fried steak type product, or breaded beef patty that is heated-treated but not fully cooked)?**

NOTE: If yes, answer the NRTE FSA Tool.

☐Yes

☐No

M58 **Briefly describe the products produced, and how the food safety system information and sample results are supplied to the buyer(s). Describe how the establishment utilizes intended use and supports its assertion that the products are used as intended. Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

Click here to enter text.

M59 **Does the establishment consider STEC as hazard reasonably likely to occur in the HACCP system?**

☐Yes

☐No

M60 **Does the establishment remove any lymph nodes?**

☐Yes

☐No

☐No, lymph nodes not present

Antimicrobial Treatment for Slaughter and Further Processing (M61 – M67)

This section is designed antimicrobial treatments (e.g., CCPs, prerequisite programs, or other programs) that support decisions in the hazard analysis.

The EIAO is to document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.

M61 **Does the establishment apply antimicrobial treatments (e.g., CCPs, pre-requisite programs, or other programs)?**

☐Yes – If Selected, answer the following questions M62,M63,M64,M65,M66,M67

☐No

M62 **Does the supporting documentation show the antimicrobial treatment is safe and suitable (FSIS Directive 7120.1, No Objection Letter [NOL], or New Technology Table [FSIS website, Regulatory Compliance, New Technology])?**

☐Yes

☐No

M63 **Does the supporting documentation show the expected reduction of the target pathogen described in the hazard analysis?**

☐Yes

☐No

M63 **Has the establishment incorporated all appropriate critical operating parameters (concentration, temperature, time, pressure, etc.)?**

***Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If there are no such findings, leave the free text box blank.**

☐Yes

☐No

M63 **Does the establishment apply the antimicrobial treatment according to the supporting documentation (complete coverage, contact time, concentration, etc.)?**

If no, briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.

☐Yes

☐No - Click here to enter text.

M64 **Does the establishment require all antimicrobial treatments to be implemented and functional during production (i.e., Multi-Hurdle effect)?**

☐Yes - If selected, answer the following questions M65

☐No

M65 **In the event of a worst-case scenario when not all antimicrobial treatments are operational, does the establishment have support that the remaining antimicrobial treatments will adequately reduce the pathogen to an acceptable level?**

☐Yes

☐No

☐ Each antimicrobial treatment is required during production

M66 **If applicable, briefly describe any vulnerability or noncompliance the antimicrobial treatments applied, the critical operating parameters for each, and include any situations when the antimicrobial treatments are not operational.**

Click here to enter text.

Sampling and Testing for Slaughter and Further Processing (M68 – M89)

This section is designed to assess whether the establishment's sampling and testing programs that are part of the establishment's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program), are designed appropriately and performed under validated conditions, and that the establishment reacts appropriately to sampling results.

As instructed in FSIS Directive 5100.1, the EIAO is to:

- **Directly observe the establishment collecting samples according to its supporting documentation if the establishment conducts sampling during the course of the FSA;**
- **Review establishment sampling results from the previous 60 days in establishments; and**
- **Document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.**

References:

1. ***Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-producing Escherichia coli (STEC) Organisms or Virulence Markers*;**
2. ***FSIS Compliance Guideline for Controlling Salmonella in Market Hogs***
3. ***Foodborne Pathogen Test Kits Validated by Independent Organizations*** **- a database to determine whether the method used by the establishment is fit for purpose and performed under validated conditions.**

M67 **Does the establishment conduct sampling and testing for Salmonella?**

☐Yes - If selected, answer the following questions M68,M69,M70,M71

☐No

M68 **Does the establishment maintain adequate support for the sample collection method? (sampling frequency, sample collection method, sampling portion, aseptic technique, etc.)**

☐Yes

☐No

M69 **Does the establishment maintain adequate support for the testing method? (test portion, fit for intended use, validation, etc.)**

☐Yes

☐No

M70 **Briefly describe the sample collection methodology, sample portion, testing methodology, test portion, and your observation of the sample collection. Briefly describe any vulnerability or noncompliance and assess the impact those findings have on food safety.**

Click here to enter text.

M71 **Summarize how the establishment addresses positives, identifies trends and how the sample results for pathogens are used for decision making within the HACCP system. Briefly describe any vulnerability or noncompliance and assess the impact those findings have on food safety.**

Click here to enter text.

M72 **Does the establishment conduct any other sampling and testing for microorganisms (including pre-harvest) that were not described above? (equipment, environment, etc.)**

☐Yes

☐No

M73 **Does the establishment maintain adequate support for the sample collection method? (sampling frequency, sampling method, sampling portion, aseptic technique, etc.)**

☐Yes

☐No

M74 **Does the establishment maintain adequate support for the testing method? (test portion, fit for intended use, validation, etc.)**

☐Yes

☐No

M75 **Do the establishment employees perform the sampling as described in the sampling protocol (aseptic technique, sample size and type, lab methods)?**

☐Yes

☐No

M76 **Briefly describe the sampling and testing methodology and frequency, and summarize how the sample results are used within the HACCP system. Briefly describe each positive or unacceptable result over the past 60 days, and the actions taken by the establishment. Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

Click here to enter text.

M77 **Summarize how the establishment addresses positives, identifies trends and how the sample results for other microorganisms are used for decision making within the HACCP system. Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

Click here to enter text.

STEC Sampling

M78 **Does the establishment conduct sampling and testing for STEC?**

☐Yes - If selected, answer the following questions M78,M79,M80,M81,M82

☐No

M79 **Does the establishment maintain adequate support for the sample collection method? (sampling frequency, sample collection method, sampling portion, aseptic technique, etc.)**

☐Yes

☐No

M80 **Based on your observation, was the establishment conducting the sample collection per the supporting documentation? (sample collection method, sample location, sample portion or dimension, sample weight, etc.)**

☐Yes

☐No

☐Sample collection not observed

M81 **Does the establishment maintain adequate support for the testing method? (test portion, fit for intended use, validation, etc.)**

☐Yes

☐No

M82 **For each sample collection protocol (trim, primals/subprimals, ground beef, AMR, variety meats, etc.), briefly describe the sample collection methodology, sample portion, testing methodology, test portion, and your observation of the sample collection. Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

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Click here to enter text.

M83 **Summarize how the establishment addresses positives, identifies trends and how the sample results for STECs are used for decision making within the HACCP system. Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

Click here to enter text.

High Event Period (HEP)

References:

1. ***FSIS Directive 10,010.3**, Traceback Methodology for Escherichia coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim;*
2. ***Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-producing Escherichia coli (STEC) Organisms or Virulence Markers;***

M84 **Does the establishment have HEP procedures and/or similar program?**

☐Yes - If selected, answer the following questions M85,M86,M87,M88

☐No

M85 **Using the agency's HEP guidance as a reference (localized HEP = ≥3 positives in 10 samples and systematic HEP = ≥7 positives in 30 samples), does the program include supportable HEP criteria (FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers)?**

☐Yes, the criteria is based on the FSIS's recommendations

☐Yes, the criteria is based on other supportable statistical analysis

☐No, the criteria is not supportable

☐Other describe: Click here to enter text.

M86 **Does the HEP outline the actions to take on all associated products (e.g. primals/subprimals, parts, associated trim, etc.) during the HEP?**

☐Yes

☐No

M87 **Describe the HEP criteria, and the role of intended use in the establishment's evaluation of all associated products entering commerce. For each HEP in the last 6 months, summarize the sample results, how the HEP was determined, and the actions taken on all associated products produced. Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

Click here to enter text.

M88 **Describe the establishment HEP investigation process, including sanitary dressing implementation analysis. Summarize any associated corrective actions and the results of any reassessment. Briefly describe any vulnerability or noncompliance and assess the impact your finding have on food safety.**

Click here to enter text.

Instruction: Meat Tool Summary:

This question is designed to focus on the <u>most significant</u> noncompliance or vulnerability findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. Summarize the findings that bear most

directly on the FSA recommendation with respect to what action, if any, is necessary with respect to the establishment's HACCP system. The answer to this question is to be used to construct the Executive Summary.

M89 **Summarize in up to three bullets any vulnerability or noncompliance findings identified in the Meat Tool that have an impact on the establishment's ability to produce safe, wholesome, unadulterated product and are critical to determine a FSA recommendation.**

Click here to enter text.