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Evaluation of surveillance system for post market activities on pre-packaged foods in Greater Accra Region, Ghana, 2021

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ABSTRACT

Objectives: This evaluation was to assess the usefulness and attributes of the surveillance system for post market activities on pre-packaged foods in the Greater Accra Region of Ghana and also to determine if the systems objectives are being met.

Methods: A descriptive cross-sectional design was used for the evaluation. Data/records on Food Market Surveillance collected between 2018 and 2020 was reviewed and key stakeholders involved in the Food Market Surveillance interviewed using a semi-structured questionnaire. Surveillance operations were also observed. Quantitative data was analyzed using descriptive summary statistics. Information gathered from interviews were put under themes.

Result: Some policy decision taken were based on analysis of data from the surveillance system. The system is useful in detecting trends signaling changes on label of registered prepackage food products. The system can permit assessment of the compliance of levels of importers/manufacturers; however, such analysis was not done. The system involves single step notification and processing steps and can incorporate data from other systems. Some retailers perceived the system as a hindrance to business. Completion of notification forms takes 2–5 min and 1–5 working days to process and take regulatory action. The surveillance system had a data accuracy and completeness of 94.6% (194/205) and 94.1% (193/205) respectively with less than 0.1% (3/95) double entries. The system did not have any data validation process or team in place.

Conclusion: The system was partially meeting its intended objectives and found useful despite some gaps and challenges observed. The system is simple, flexible, accepted by most of the stakeholders and covers almost the entire districts in the Greater Accra Region. We recommend that data validation process or team be instituted to ensure reliability of data generated for policy and regulatory decisions.

1. Introduction

Unsafe food account for 600 million cases of foodborne diseases and 420,000 deaths worldwide. 30% of these deaths associated with foodborne disease occur among children under 5 years of age. WHO has estimated that 33 million years of healthy lives are lost due to eating unsafe food globally each year and this may even be an under-estimation [1]. In Ghana, outbreaks of foodborne diseases have been associated with food contamination at various stages of the food supply chain [2–5].

Post market surveillance and product quality monitoring are some of the regulatory measures instituted by countries to ensure their food supply chain is not compromised. Post market surveillance differ worldwide among each country. In the European Union it is the responsibility of each individual Member State to develop and sustain their internal post market surveillance due to the differences in resources, priorities and legislative framework [6]. However, the Rapid Alert System for Food and Feed is used in European Union as a key tool to ensure the flow of information that enable prompt responses when risks to public health are detected in the food chain [7]. In the USA, the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration has implemented safety surveillance program and

Abbreviations: FDA, Food and Drugs Authority; IECD, Import and Export Control Department.

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the CFSAN Adverse Event Reporting System (CAERS) as a means of monitoring food products in trade [8].

In Ghana, the FDA has instituted a system to ensure the safety of the food supply chain. The system is in two parts. One involves granting import clearance permit to food importers and conducting physical inspection of consignment before imported foods are cleared by Customs. The other is the post market surveillance activities of products on the market. This involve collecting data on compliance of imported and locally manufacture foods on the retail market of all the 16 regions in Ghana. The system covers all regulated products of FDA, however with food only pre-package foods are monitored.

Data for the surveillance system is collected through routine activities of FDA officers on the retail market, consumer complaints received at FDA and detention notifications received from the FDA officers at the points of entry. The data collected is used to determine the compliance of the food product and the regulatory actions that need to be taken. Some regulatory actions or public health actions taken include product relabelling, product recalls and safe disposal of products.

Lapses or weakness in Post market Surveillance of food could result in a compromised food supply chain due to contaminations which render food unsafe for consumption. In September 2008, the food supply chain of China was compromised with melamine contamination of Infant Milk due to weak post market surveillance. This resulted in 300,000 Chinese infants and young children being affected with 6 deaths. These infants and young children were diagnosed as having kidney and urinary tract problems [9,10]. The world's largest Listeriosis outbreak was recorded in South Africa in 2017 which was characterized by a progressive increase incidence of listeriosis cases from January 2017 to July 2018 [11–13]. A total of 1060 laboratory-confirmed cases of listeriosis were recorded, with 216 deaths. Epidemiological investigations linked the cause of the outbreak to a ready-to-eat processed meat products from a food production facility contaminated with L. monocytogenes. As result of the outbreak, surveillance systems for the food chain were strengthened in the South African to assist in the prevention and early detection of both sporadic cases and outbreaks. In Ghana, the FDA warned the public over the consumption of palm oil after its surveillance system indicated the 98% of the palm oil on the market were contaminated with Sudan IV dye 55 [14,15]. However, no associated morbidity or mortality was reported. No evaluation of the surveillance system has also been conducted to see if the system is meeting its objectives.

This work is on the evaluation of the surveillance system for post market activities on pre-packaged foods in the Greater Accra Region of Ghana. The system and its attributes were evaluated to assess if its objective of ensuring compliance of pre-packaged food is being achieved and if the surveillance system is useful in improving food safety.

2. Methods

2.1. Research design

A descriptive cross-sectional design was used for the evaluation, adapting the CDC Updated Guidelines for Evaluating Public Health Surveillance Systems as a guide. Data/records from the Food Market Surveillance Department (FMSD) of the FDA was used for all the levels of review. Data collected between 2018 and 2020 was used in the study and this was retrieved between the period of April to May 2021. In assessing the objectives, attributes and usefulness of the surveillance system, a semi-structured questionnaire was developed to aid in both the qualitative and quantitative data collection process.

2.2. Data collection

A semi-structured questionnaire (see appendix 2) was administered via face-to-face and telephone interviews with stakeholders regarded to play key roles in the operation of the surveillance system. Purposive sampling technique was used in selecting participants for the interviews. Consideration was also given to the availability and willingness of stakeholder to participate.

Records reviews were conducted by examining weekly and monthly data on only prepackaged food products imported and those manufactured locally. Records of two database were reviewed, the database on Product Verification (PV) which contain information on notification from the Point of Entry (PoE) by officers of the IECD and database on Post market (PM) activities which contained information on consumer complaints and routine inspections.

Paper records that had been electronically captured were randomly selected for review and comparison with the electronic databases. The sample size was calculated using EpiInfo StatCal (expected frequency of 50%, design effect of 1 and 5% margin of error at 95% confident level).

2.3. Assess whether the PMS system is meeting its intended objectives

The system was assessed to determine if is meeting its intended objectives. This was done by reviewing policy decision taken to find out if any were based on the surveillance data. Also, record and trends of the level of non-compliant food products on the market were reviewed. Risk analysis conducted by FDA was reviewed to determine if surveillance data was used.

2.4. Assessing level of usefulness of the system

The usefulness of the system was assessed to see if the systems was able to detect trends signaling changes in prepackage food products, detect changes in compliance of registered food product and provide estimates of the compliance levels of food products. The system was also assessed to establish if the surveillance system was able to stimulate research likely to lead to control or regulatory policy. Also, records were reviewed to assess how the data generated from this system was being used to improve policy or decision making.

2.5. Assessing system's attributes

When assessing the systems attributes, the Updated Guidelines for evaluating public health surveillance systems by the Centers of Disease Control and Prevention was used. The semi-structured questionnaire developed was used to collect information that describe the attributes of the surveillance system. Details of how attributes were assessed can be found in the supplementary file.

2.6. Data analysis

The data was analyzed using both qualitative and quantitative descriptive methods. Thematic analysis was used in summarizing qualitative data gathered by means of the interviewer-administered questionnaire. By this approach, the participants' responses were grouped under thematic areas. Attributes that achieved less than half of all indicators assessed were rated as poor, those that achieved between 50 and 80% of indicators were rated fair while those that achieved almost all indicators assessed were rated as satisfactory. Frequencies, and proportions was used in analyzing the quantitative data. Epi Info 7 and Microsoft Excel 2016 software was used in performing these analysis and results presented as texts and graphs.

3. Results

3.1. Demographics

A total of 30 stakeholders who are involved in the operations of the surveillance system were interviewed during the evaluation. Fifteen (50%) of the interviewees were FDA officer involved in inspections activities, data entry and processing, 10 (33.3%) were importer/clearing agents of prepackage foods and 5 (16.7%) were retailers of prepackaged

foods (see Table 1). The interview was carried out at the different levels from the Municipal/district level via regional level to the National level. The respondents for evaluation at facility level (retailers of prepackage food) were from the Ga South, Ga Central, Ayawaso West Wugon, Tema and Accra Metropolitan Assemblies.

The Product Verification (PV) database had a total of 3418 records (Fig. 1) whiles the Post market (PM) database had a total of 439 records. Total of 345 and 205 paper records that had been electronically captured were randomly selected for review and comparison with the PV and PM electronic databases respectively.

3.2. Description of surveillance system

The surveillance system covers all pre-packaged food products on the Ghanaian market, both locally manufactured and imported. Notifications are usually received through telephone or paper forms from consumers, retailers of prepackaged food and the IECD/FMSD officers of FDA (Fig. 2). The notifications are in three categories; product verification (PV) notice from officers of IECD on imported food product, product complaints from consumer/retailers and routine inspection notice from officers of the FMSD. All notifications received are captured into an electronic database. Information captured include, product details, country of origin, importer/manufacturer, location of importer/manufacture, category of non-compliance, date of notification and action taken. Samples are taken to accompany the notifications when its necessary. These samples are submitted to the laboratory for analysis and result used in taking regulatory decision.

Data from the system is analyzed every quarter by a member of the FMSD and reviewed by the Head of FMSD. Analysis performed included trends on number of PV notices received, number of PM activities carried out and number of outlets visited. The quarterly or annual report are organized in tables and charts before submission to the Deputy Chief Executive-Food and the Monitoring and evaluation department (M&ED) for policy decisions. Submission is done both in paper and electronic form.

3.3. Surveillance system meeting its intended objectives

Some policy decision taken were based on analysis of data from the surveillance system. Decision to sanction an importer/manufacturer and on safe disposal of products are based on information from the system. However, no records and trends of the level of non-compliant food products on the market was captured by the system. Also, no record or evidence indicated that risk analysis conducted by FDA were done using data from the surveillance system.

Table 1
Demographic characteristics of Respondents/Stakeholders.

Characteristics of Respondents	Number(n=30)	Percentage (%)
Age		
<25	2	6.7
25–35	16	53.3
>35	12	40.0
Occupation		
Food importer/Clearing agent	10	33.3
Food retailer	5	16.7
FDA inspector	15	50.0
Sex		
Male	6	20.0
Female	24	80.0
Religion		
Christians	15	50.0
Muslim	8	26.7
Others	7	23.3
Years of working experience		
<1	4	13.3
1–5	8	26.7
>5	18	60.0

3.4. Level of usefulness of the system

The system is useful in detecting trends signaling changes on label of registered prepackage food products. The system, in 2019, stimulated the sampling and testing of imported tomato paste. This research led to the implementation of regulatory policy at the point of entry for imported tomato paste. Since January 2020, all imported tomato pastes are examined for adulterants before been released onto the market. Data from the system is used to take regulatory decisions such as sanctioning of importer/manufacturer, product recalls and safe disposal of non-compliant products. The system is able to permit assessment of the compliance levels of importers/manufacturers, however, such analysis is not being done. The system is unable to provide estimates of the compliance levels of prepackaged food products on the market for a particular time period.

3.5. System attributes

3.5.1. Simplicity

All respondents understood when a product is classified as non-compliant and were able to state the case definition which they considered was easy. The systems notification and processing operations involve single step processes and these were easy to follow by stakeholders (Fig. 3). For instance, the system requires one inspection to confirm a non-compliance. Notifications are received through WhatsApp, emails and paper forms. The system is partially computerized and even though paper-based notification is used, these are recorded and transmitted electronically. Feedbacks to stakeholders are however done by means of letter writing.

3.5.2. Flexibility

The system has the ability to incorporate new changes without interrupting or affecting the system functions/objectives. The system is able to incorporate data from the PoE surveillance system and product functionality software (food products register). Records reviewed in the last 3years indicated a revert in transmitting notification from IECD via WhatsApp snapshot to paper. This however affected the response time of officers to IECD notification, resulting in difficulty in scheduling stakeholders quickly for inspection.

3.5.3. Data quality

The quality of data improved from 2018 to 2020, with less incomplete data observed in the database over the years. The data organization also improved over the years (2018–2020) with clear field names and descriptions, making it easy to understand data captured. Accuracy of data captured in the PM database is 94.6% (194/205). Majority, 94.1% (193/205) of the notification from FMSD officers/clients were completely filled and these were completely captured electronically However, no data was captured on total number of prepackaged products routinely inspected and less than 0.1% (3/95) electronic double entries were observed (mostly in 2018).

Accuracy of data captured in the PV database is 98.0% (338/345). Eighty-five percent (295/345) of the IECD notifications were completely filled and these were completely captured electronically. The system did not have any data validation team in place or data validation processes.

3.5.4. Acceptability

Acceptability increased over the years 2018–2020. This was evidenced in the number of inspection activities and IECD notifications received and processed. More, 1327 notifications were received in 2020 as compared with 855 in 2018 and more, 167 inspection activities were carried out in 2020 as compared with 95 in 2018. Officers indicated that it takes 2–5 min to complete a notification form and 1–5 working days to process and take regulatory action.

However, most retailer and importers perceived the surveillance system as a hindrance to business. Hence their unwillingness to

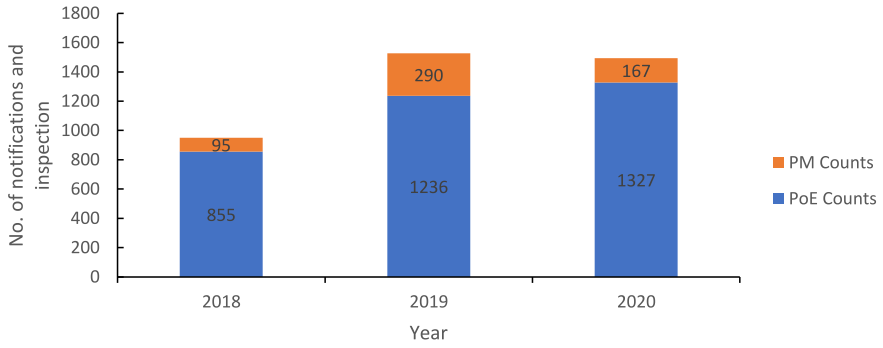

Fig. 1. Yearly Point of Entry (PoE) notifications and routine post market(pm)inspections in Greater Accra Region, 2018–2020.

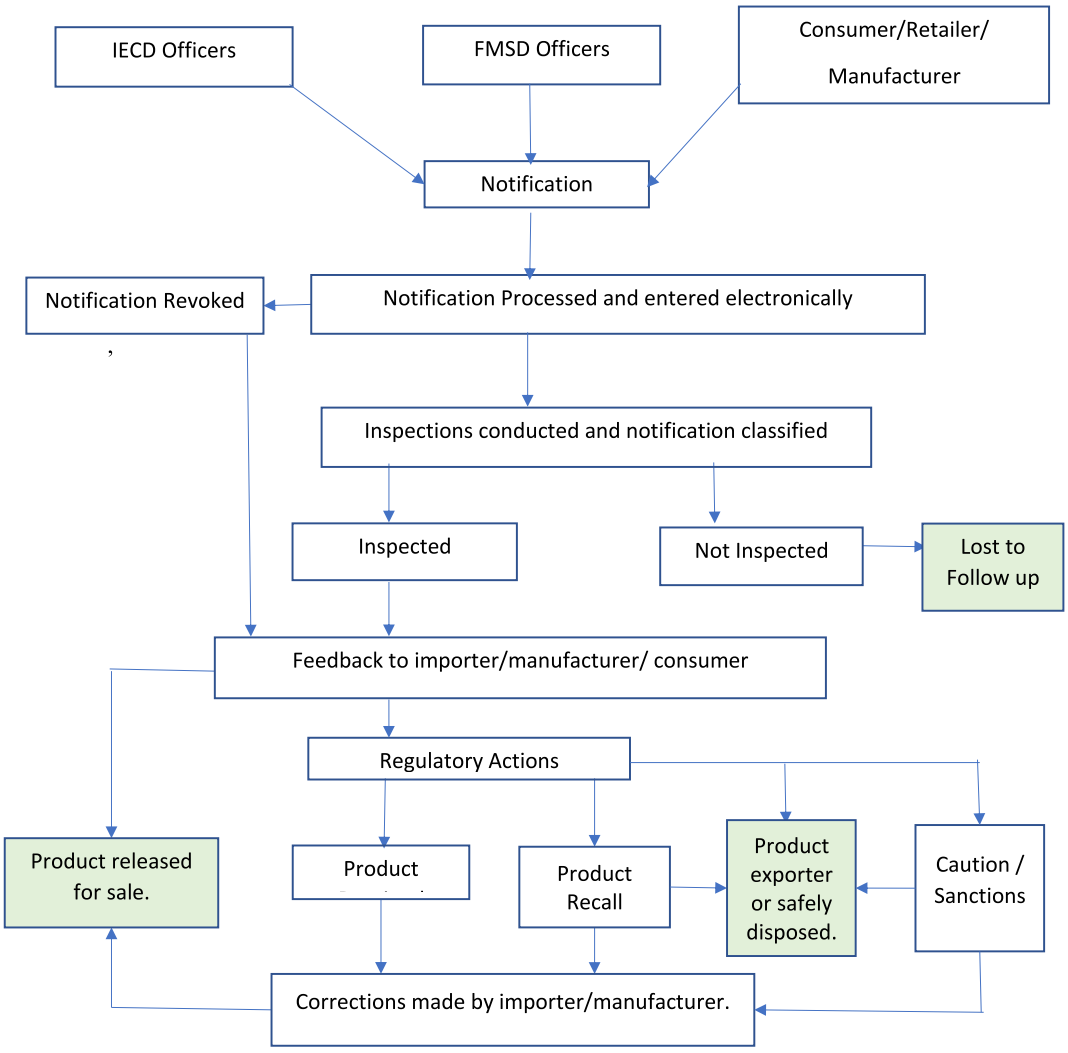

Fig. 2. Schematic flow of the surveillance system for post market activities on pre-packaged foods in Greater Accra Region, May 2021.

voluntarily notify FDA of any non-compliant prepackage product. Most of the importer/clearing agents gave wrong contact details or refused to give location of warehouse for PV inspections to be done. Hence the PV database had most, 70% "not worked on" status for IECD notification received.

3.5.5. Sensitivity

The system captured a total non-compliance of 950, 1265 and 1494 in 2018, 2019 and 2020 respectively. However, the system could not estimate the percentage of non-compliant products on the market. There was also no yearly target set for non-compliant product on the market for comparison with actual number of non-compliant products observed in the year. No data was also captured on point of entry and manufacturer of a non-compliant products observed on the market.

3.5.5.1. Positive predictive value (PPV). The mean PPV for the system

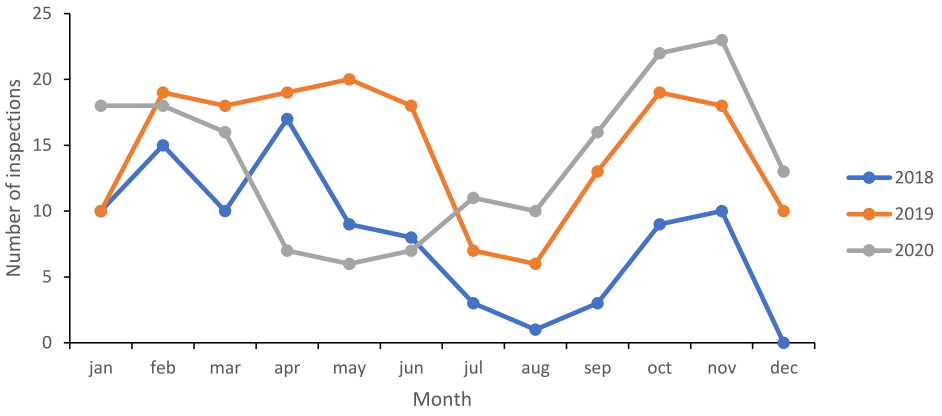

Fig. 3. Monthly trend of Post Market inspections carried out in Greater Accra Region, 2018–2020.

over the period 2018 to 2020 was difficult to estimate. No records on revoked notifications were available for 2018. However, the PPV for the system was 92.6% (1009/1090) and 85.0% (323/380) in 2019 and 2020 respectively.

3.5.6. Representative

All the various categories of prepackaged food products were captured by the surveillance system. Product compliance from the various category/scale of retailers (large, medium, small and table top), importer and manufacturers were also captured in the surveillance system. The routine PM inspections covers 28 out of the 29 districts in Greater Accra Region. The district not covered was Kpone Katamanso district. The monthly number of inspections were similar across the years (Fig. 3). There is always a decrease in PM inspection visits conducted between July and August before it starts increasing again from September each year.

3.5.7. Timeliness

The operations/process of PMS has no documented timelines. However, records reviewed for 2019 and 2020 indicated that the time frame for responding to notification/complaints was between 1 and 5 working days. The IECD notifications were also responded to within 5 working days upon receipt of notification. The response usually starts with contacting client/complainant via telephone within 24hrs upon receipt of notification. The time frame for public health or regulatory actions to be taken was not dependent on FDA alone but other stakeholders. Example the time frame for carrying out safe disposal of non-compliant product depends on the availability of the Metropolitan, Municipal and District Assemblies (MMDAs), (they provide equipment for the safe disposal) which may take a maximum of 10 working days.

3.5.8. Stability

The data in the two electronic databases are backed up onto an external hard drive every Friday of the week. All the paper notifications are also filed as backups. All the computers use UPS battery to maintain temporary power during power failures until the generator system restore power to the offices. The computer housing the systems database crashed during the last two years but the data was restored using the back-up from the external drive.

The routine post market inspections are mostly conducted by National Service Personnel (NSP) with supervision from Regulatory Officers. However, the quantum of products inspected during a routine post market inspection reduce drastically every August (Fig. 3) when there is no NSP in the department. The system is financed from the FDA annual budget allocated.

4. Discussion

The surveillance system for post market activities on pre-packaged foods in Greater Accra region was being run by officers that have adequate work experience (2–9 years) with females being the majority, 81.3%. The systems starting point is the end point of the surveillance system for imported food products and the market authorisation process of both local and imported food product.

The system was partially meeting its intended objectives. Some surveillance system evaluations conducted in Ghana for diseases have also concluded that the systems evaluated were not fully achieving their intended objectives [16–20]. A study in Brazil which used a different evaluation method to evaluate the Food and Nutrition Surveillance System (SISVAN) of the State of Minas Gerais, Brazil also concluded that the system was not being used to its full potential and that the data generated from the system was not used for planning, management and evaluation of nutrition services [34]. This conclusion however contradicts conclusions made by studies on evaluation of post market surveillance systems for drugs, one of the regulated products of FDA. These studies were on Adverse Drug Reaction (ADR) and Adverse Events Following Immunizations (AEFI) surveillance systems (two similar systems also implemented by FDA) implemented in other countries. One such study was on the evaluation of the AEFI surveillance system in Harare City, Zimbabwe in 2016 which concluded that the performance of the system was good due to high health worker knowledge [21]. Hence improving stakeholder knowledge on the surveillance system may improve achievement of the system's objectives.

One of the objectives of the surveillance system for post market activities was to monitor quality of pre-packaged food products to inform policy makers for public health interventions and regulatory decisions. The quality of a food product is characterized by the content, packaging and labeling of the product meeting a set of prescribe standards [22]. The system is however, monitoring trends signaling changes on label/-packaging and not the content of the food products. This observation varies from the post market surveillance systems implemented by member states of the EU, where member states periodically sample and test pre-package food products at the Points of Entry and on their markets. Notifications are then sent to the Rapid Alert System for Food and Feed (RASFF) when changes are detected in the quality of the food product [7]. This is done to monitor the quality and safety of food products on the markets of EU member states. The lack of periodic sampling and testing of prepackaged foods in Ghana could compromise the food value chain due to changes in composition of preapproved food products. A study conducted in Iran on commercial canned tuna fish revealed that 36.6% of samples had higher histamine contents than the levels recommended by the USFDA and what was approved for

marketing in Iran [23].

The surveillance system was unable to estimate the compliance levels of prepackaged food products on the market for a particular time period and even though the system permits the assessment of the compliance level of importer/manufacturers this is not being done. The lack of non-compliance prevalence and importer/manufacturer compliance trend makes it difficult to conduct risk assessment of products and risk level characterization of importer/manufacturer. Hence data from the surveillance system not fully utilized in policy decision making.

The system was found to be simple and flexible. The system involves single step notification and processing steps and can incorporate data from other systems. The system requires one inspection activity for regulatory decision to be taken on a notification. Data quality was generally fair for inspection activities (PM database) but satisfactory for IECD notifications (PV database). Acceptability was generally satisfactory. The simplicity and high level of acceptability impacted favourably on the data completion (94.1%) and accuracy (94.6%). These outcomes where similar when compared with a study that evaluated the post market surveillance system on drugs (Antiretroviral adverse drug reactions pharmacovigilance) in Harare City, Zimbabwe in 2017 [24]. The study found data quality for the systems to be 0.75–1.0 and concluded that the system was simple and acceptable despite it being unstable.

Even though the surveillance system for post market activities on pre-packaged foods did not have documented timelines, the time frame (1–5 working days) for processing notification was good. This could be attributed to the simplicity of the system and high level of acceptability among officers of the FDA. Acceptability was however low among importers/clearing agents and retailers. Most of them perceived the system to hinder business operations. This has resulted in the provision of wrong contact details by importers/agents and their unwillingness to avail their detained products for inspection by FDA officers. Hence the high number (70%) of notifications had not been worked by the FDA officers. The absence of data on percentage compliance of products on those markets makes it difficult to estimate the percentage of these importers/agents that do not accept the system. The lack of data on Point of Entry of imported non-compliant products also makes it difficult to implement regulatory policies to improve the acceptability of the importers and the levels of non-compliant product on the market.

The system is able to detect and respond to non-compliant pre-package food on the market as evidenced by the total of 3857 non-compliant products captured by the system. Out of these 92.6% and 85.0% were true non-compliant products (PPV) in 2019 and 2020 respectively. This is an indication of increasing misclassification of products as non-compliant by stakeholders. There is therefore the need to refresh or sensitize stakeholder especially IECD officers on the case definition for non-compliant pre-packaged food product.

The system was found to be stable with dedicated resources, both human and financial. The use of National Service Persons is however impacted negatively on the stability of the system especially in the month of August every year. In August every year the quantum of products inspected on the field and the PM activities drops (Fig. 3) when the department does not have National Service Persons. The system therefore needs to find way of retaining these National Service Persons until they get replacements in September for each year. The system can also consider using permanent staff to address this challenge. With regards to representativeness, the system covers all pre-packaged foods in almost all the districts (expect Kpone Katamanso) in Greater Accra Region. The surveillance system also collected data all year round.

5. Conclusion

The Surveillance System for Post Market Activities on Pre-packaged Foods in Greater Accra Region instituted by the FDA was partially meeting its objectives, despite some gaps and challenges observed. The system is useful in detecting trends signaling changes on label of registered prepackage food products and able to stimulate research likely to lead to control or regulatory policy. However, the system is unable to provide estimates of the compliance levels of prepackaged food products on the market for a particular time period. The system is simple, flexible with good data quality, accepted by most of the stakeholders and representative of the entire districts in the Greater Accra Region. The sensitivity, predictive value positive (for some years) and timeliness for the system was difficult to assess quantitatively for the entire period due to the systems inability to capture the requisite data needed.

Highlights for what this research findings mean for public health in practice.

- We identified that the system was partially meeting its intended objective of monitoring the quality of pre-packaged food products, to inform policy makers for public health interventions and regulatory decisions
- The system was simple, highly acceptable among stakeholders and has. The ability to incorporate new changes without interrupting or affecting the system functions/objectives.
- Our results are consistent with some surveillance system evaluations conducted in Ghana for diseases, which also concluded that the systems evaluated were fairly meeting their intended objectives. Such findings may have implications on the effectiveness and efficiency of surveillance systems in Ghana.

Author contributions

Benjamin Osei-Tutu: Conceptualization, Methodology, Original draft preparation' **Eunice Laryea:** Conceptualization, Reviewing **Rita Agyekumwah Asante:** Reviewing, editing **Delese A.A. Darko:** Reviewing, editing.

Competing interests

The authors declare that they have no competing interest as far as this work is concerned. All views expressed in this work are views of the authors and does not represent the views or position of any institution.

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Ethics approval and consent to participate

Ethics approval and participant consent was not necessary as this study involved the use of a de-identified data obtain as part of collected by the Food and Drugs Authority (FDA) during their Post Market Surveillance activities. All the required approvals for the use of data were obtained from the Chief Executive Officer of FDA, Ghana.

Declaration of competing interest

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us. We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual

property.

We understand that the Corresponding Author is the sole contact for the Editorial process (including Editorial Manager and direct communications with the office). He is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs. We confirm that we have provided a current, correct email address which is accessible by the Corresponding Author and which has been configured to accept email from.

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Appendix A. Supplementary data

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