The legal applications of official supervision and controls based on hygiene, the evaluation of microbiological criteria from past to present in Turkey: Review

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ARTICLE INFO

ABSTRACT

General and specific hygiene requirements of the food facilities were published in compliance with the European Union regulations in 2010 in issue No. 29 under the section headedline “hygiene” within the frame of Law No. 5996 on Veterinary Services, Plant Health, Food and Feed. Accordingly, the manufacturer has to follow the rules mentioned in “Regulation on Food Hygiene” and “Regulation of Special Hygiene Rules for Animal Food” to provide food hygiene in all phases of production, processing and distribution, including the primary phase. The criteria mentioned in the regulation appendices are in key position in the control and prevention of microbiological hazards. No provision exists regarding any microbiological detection out of legal criteria. Pathogens resulted in foodborne outbreaks or cases have an important role in legal sanctions. The legal application for official controls based on hygiene rules, legal regulations in microbiological criteria and scientific research data have been reviewed.

Citation: Özçakmak S, Var I, Akbulut O. The legal applications of official supervision and controls based on hygiene, the evaluation of microbiological criteria from past to present in Turkey: Review. J Food Safe & Hyg 2016; 2(1-2): 1-7.

1. Introduction

The approach to food safety criteria in our country has undergone a radical change in compliance with the rapid changes in the world and the European Union (EU). There have been comprehensive changes regarding Food Safety, Veterinary Medicine, and Plant Health policy within Chapter 12: Food Safety, Veterinary and Plant Health Policy of the EU. In terms of Chapter 12, Law No: 5996 on Veterinary Services, Plant Health, Food and Feed, which forms the legal basis to the secondary regulations in concordance with the EU was issued on December 13, 2010 (1). In the meeting with the European Commission, changes in a very large field have taken place. The “Quadripartite Hygiene Pack” regulations (852/2004/EC, 853/2004/EC, 854/2004/EC, 882/2004) have been transferred to national legislation. Furthermore, “Microbiological Criteria for the Foodstuffs” numbered 2073/2005/EC has been issued, in parallel with the European Parliament and Council Charter (2,3,4). The Food Hygiene Regulation (2) includes the rules regarding the food hygiene that the food producer has to follow, from the primary production to the last offer to the consumer of the food, to provide a protection to the consumer in terms of food safety. Food manufacturers are inspected in the official controls according to Law No: 5996 to find out whether they are suitable for hygienic conditions. If the process area is the case, it should be applied as mentioned in the appendix “Production Hygiene Criteria” for quality control criteria (1,4). In this review paper, we discussed and tried to evaluate the procedures applied in the hygiene based food control, legal sanctions, past and present changes on the microorganisms/toxins/metabolites in the microbiological criteria regulation.

2. Controls based on hygiene, and the applied legal actions

General and specific hygiene requirements should...
be carried out to provide food safety along the food chain beginning from the primary production to the final consumer. Even though the “Manual of Good Hygiene Practices (GHP)” prepared according to the existing regulations is optional for the use of the food producer, it has a great importance for being a guide to the GHPs regarding the control of the hazards (2).

During the inspections and controls implemented according to Law No: 5996 food legislation, the criteria in the “Official Control Form for the Certified/Registered Manufacturers” that appears in “Official Food Control and Administrative Sanctions Procedure” (5) appendix 2 is consulted. During the official control process, in case the whole or a part of the location poses a danger regarding the human health and food safety, and requires urgent precautions, the actions of the whole part or the part of the production that poses a danger are stopped, and these are not permitted to produce until they eliminate the nonconformity.

If the analysis is not suitable for the limits stated in the Turkish Food Codex Regulation on Microbiological Criteria, a 16.058 TL administrative fine (AF) is applied according to the article 40, paragraph (d) due to the article 21, paragraph (5) in 2017. If these products have any potential health risk for the humans, all are recollected from the market, the expenses belonging to the producer, and are passed property to the public. If the indecency is only confirmed by the procedures based on the GHPs and requires urg.

3. Legal changes regarding the microbiological criteria and changes made from past to present

The analysis of microbiological criteria should be provided by the food manufacturer to be verified or confirmed by the procedures based on the GHPs and the Hazard Analysis Critical Control Point (HACCP) principles (4).

“Microbiological Criteria Regulation of Turkish Food Codex” was published in the Official Newspaper dated December 29, 2011 and numbered 28157 in conformity with the articles of 21, 22, 23, 24, 29, 30, 31, 32, and 34 in the Law No. 5996 on Veterinary Services, Plant Health, Food and Feed and Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs. Nowadays, administrative proceedings are still being applied following the criteria mentioned in the appendices of this regulation. In case the analysis of toxic secondary metabolites is required to control food safety, it has been evaluated according to the context of the Turkish Food Codex (TFC) Certain Contaminants Regulation (4).

The food safety is assured, if the analysis of the samples, that are taken with reference to the regulations related to Law No. 5996 and the Ministry’s Instructions result in compliance with the legal limits determined by the microbiological and other related regulations.

4. Changes to the microbiological criteria

4.1. Rope spore, fungi, yeast-fungi, and yeast analyses

Changes have been done in the rope spore, fungi, yeast, and yeast-fungi criteria, including the cereals, fruits-vegetables, jam-marmalade, confectionaries, and fermented milk products since 2001. The rope spore analysis has been delisted in the cereal flours since 2009. Any criteria related to the Bacillus spp., and/or its spores in the pies and pastry group is not present in the regulation since 2001. It is observed that fungi count for the milk products and meat products has been limited in the regulations published since 2001. It is considered that including yeast-fungi analysis as a “Production Hygiene Criteria” would be useful. Yeast analysis was delisted in the appendices of regulations published in 2006, 2009, and 2011. It would be useful to pay attention to the yeasts as the indicator of the microbial load of the production area in the process, to include them in the standard operational procedures, and to make it mandatory in terms of control measures (6,7,8,9). Table 1 summarizes the criteria for rope spore, mold, yeast, and yeast-mold from the beginning to the last form in TFC Microbiological Regulation.

4.2. Aerobic colony number (ACN), Escherichia coli, coliform bacteria, Enterobacteriaceae and Salmonella spp. analysis

By the changes modified in the regulations in 2011, in the criteria related with the ACN count, it is seen that these criteria are involved in meat and meat products group at most, and it was delisted from many products such as milk and milk products, cereals for breakfast, macaroni products, cocoa and chocolate products, and nutrition support.

In the notifications and regulation published over the years, it is seen that the analysis of E. coli was present in some foodstuffs, delisted from some of them. For example, the analysis of E. coli was delisted in “pies and pastries,” and “ready to consume (cooked) any kind of meat and vegetable products” in the “Convenience Food” group. Besides, E. coli analysis has been mandatory for butter and cream processed by raw milk or lower pasteurization temperature instead of pasteurized cream but delisted from pasteurized milk.
While the E. coli search did not exist in meat and meat products in the Notification No. 2009/68, it was included in the minced meat and prepared meat mixtures as “Production Hygiene Criteria” in 2011. It has been added to the codex as the “Production Hygiene Criteria” in the seafood and as the “Food Safety Criteria” in the liquid and meat among the shells of the fishery products in 2011.

Enterobacteriaceae analysis entered the codex after 2009. The Enterobacteriaceae criteria were continued in the milk products and egg products and edible ice that are not milk based since 2009, but it was delisted in the cheese from 2011, and it took part as “Production Hygiene Criteria” not in the meat and meat products but the carcass of several animals.

While coliform bacteria analysis took part in milk and milk products in the Notification No. 2001/19, 2009/6, and 2009/68, it was delisted in the products such as fermented milk products (kefir), yoghurt, fruit yoghurt, and ayran and other fermented milk products, milk skin, and cream cheeses by the regulation published in 2011. Similarly, coliform analysis was delisted in powder mixtures offered to consumption after being cooked, cocoa and products, chocolate and chocolate products, mayonnaise, and salad dressings containing mayonnaise. In the latest published Microbiological Criteria appendices published, it is seen that fecal coliforms are considered as “Food Safety.” It should be incorporated with milk and milk products, meat and meat products, fruit and vegetable products, in which the cross-contamination is most frequently seen. Table 2 summarizes the criteria for ACN, E. coli, coliform bacteria, Enterobacteriaceae, and Salmonella spp., from the beginning to the last form in TFC Microbiological Regulation.

4.3. B. cereus, E. coli 0157:H7 and coagulase positive Staphylococcus analyses

While the B. cereus analysis for the cereal flours and processed cereals for breakfast existed in the Notifications No. 2001/19 and 2006/23, It was out of these groups in the following years. It is seen that many products among the potentially hazardous foods in terms of B. cereus (cereals and bakery products, pasteurized milk, pudding, etc.) are not among the food safety criteria.
Table 2. The legal regulation made by ACN, E. coli, coliform bacteria, Enterobacteriaceae and Salmonella spp. criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>2001/19 product group</th>
<th>Official Gazette of Publication: 29.12.20128157-Product group</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACN</td>
<td>Dairy products (except cheese, butter), grain flour and grain-based products (except processed cereal products for breakfast), sugar and sugar products, confectionery products (such as a Turkish delight), shortening, frozen fruit and vegetables, dried nuts, molasses, fruit juice and nectar, tomato juice and puree, soup, cocoa and cocoa products, pasteurized vinegar, pickle and pickled products, fermented drinks, gelatin, mayonnaise and sauce, starch, baker’s yeast, black tea, chewing gum, alcohol-free fizzy drinks</td>
<td>As the criteria of food safety; mincemeat, MSM (red meat and poultry)</td>
</tr>
<tr>
<td>E. coli</td>
<td>All of the dairy products, grain flour and grain-based products, processed grain products for breakfast, frozen and unfrozen ready to cook noodle, pizza, pastry, etc., products, sugar and sugary products, puddling, etc., confectionery products, halva, shortening, ready to eat frozen or dried vegetables and fruit products, dried nuts, molasses, coconut, soup, cocoa and chocolate products, pickle and pickled products, mayonnaise and sauce, starch, black tea, coffee, chewing gum, food degree salt, alcohol-free fizzy drinks ready-to-eat daily food and snacks</td>
<td>As the criteria of food safety; fermented dairy products (kofir, yoghurt, Aryan, yoghurt with fruit, etc.), cream cheese and its products, condensed milk, starch, soy milk and foods with soybean, coffee whitener, food supplements, halva, molasses, Turkish delight, baklava and other desserts with sherbet, ezme, cezerye, hazelnut paste and peanut butter, candies, etc., ready-to-eat (cooked) all sorts of meat and vegetable meal, ready to eat all sorts of salads, charcuterie products and cold appetizers, ready-to-eat all sorts of cooked bakery products (pasta, all sorts of pastry, lahmacun, flatbread, pizza, mantı, etc.), cheese made from milk heating processed or whey, butter and cream processed by raw milk or lower pasteurization temperature. As the criteria of production hygiene; mincemeat (MSM; carcasses after skinning out but before cooling), mixtures of prepared meat, fisheries (cooked valves and shelled molluscs shelled and unshelled products), fruit, vegetables and their products (ready-to-eat chopped fruit and vegetable), ready-to-eat unpasteurized fruit and vegetable juice</td>
</tr>
<tr>
<td>Coliform bacteria</td>
<td>All of dairy products, grain flour and grain-based products (processed grain products for breakfast, frozen and unfrozen noodle, pizza, pastry, etc., products ready to cook), sugar and sugary products, confectionery products (Turkish delight), halva, fats, raw vegetables ready to consume, molasses coconut, fruit juice and nectar, ketchup, soup, products with cocoa, boza, pickle and pickled products, gelatin, starch, black tea, coffee, chewing gum, table salt, food industry salt, alcohol-free fizzy drinks</td>
<td>As the criterion of food safety; grain flour, soybean flour, and other sorts of flour (including potato flour), filo pastry, kadayif, etc., granule, semolina and all granule products, muesli, corn flakes, popcorn, puffed rice, chipssets, grain-based products, bran offered to human consumption, plain cake, plain biscuit, plain crackers, etc., coated, filled and/or flavored biscuits, cake and crackers, wafer (plain, with cream, filled, etc.) salt, soybean milk (powder), spreadsable butter, margarine and condense butter, roast coffee bean, roast pulverized coffee, coffee extract and ready to consume coffee including aromatized coffee constitute</td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td>Absent</td>
<td>As the criteria of food safety; Pasteurized milk, ice cream ice with milk, milk powder and cream powder, mixtures for ice cream, whey powder, buttermilk powdered milk-based powder products, casein and caseinate. As the criterion of production hygiene; pasteurized milk and other pasteurized liquid dairy products, milk products and whey (this criteria does not apply to the products to be further processed ) ice cream including only milk constituent, dried baby formulas (including dietary foods for special medical purposes), dried follow-on formula, egg products (pasteurized and frozen egg, egg powder, etc.), egg products, cattle, sheep, goat and horse carcass, pig carcass, edible ice not milk based (ice with fruit, sorbet, and others)</td>
</tr>
</tbody>
</table>

M3M: Mechanically separated meat, ACN: Aerobic colony number, E. coli: Escherichia coli

The coagulate Staphylococci (Staphylococcus aureus) criteria have taken place in milk, milk products and milk-based products group since 2009. S. aureus has been just involved in the “meat products that are not heat treated” by the regulation published in 2011. In addition, Staphylococal enterotoxin analysis must be done for cream cheese and its products, all sorts of ready-to-eat (cooked) vegetables and meat food, etc., all sorts of ready-to-eat salad, charcuterie products, cold snacks, all sorts of ready-to-eat (cooked) bakery products, and all sorts ready-to-eat (cooked) desserts. Moreover, coagulate positive staphylococcus analysis could be done for suspected of food safety in all of the “ready or not-ready-to-eat foods” (4).

While E. coli O157:H7 criteria did not exist in the earliest published Notifications No. 2001/19 and 2006/23 2009/6 in Turkey, the criteria have been in the processed fruit-vegetable products in the

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Notification No. 2009/68 and the regulation in 2011. On the other hand, it was delisted from the cheese (excluding cream cheese), offal, and fruit vines by the regulation published in 2011. The requirement of E. coli O157:H7 analysis has been just implicated in the raw and processed fruit and vegetable products, and just some meat and meat products by the latest legal arrangements (4). Enterohemorrhagic E. coli analysis should be reviewed of the broader food group especially cheese processed from raw milk in the future (10,11). Table 3 summarizes the criteria for B. cereus, E. coli O157:H7 and coagulase positive Staphylococcus from the beginning to the last form in TFC Microbiological Regulation.

4.4. Clostridium perfringens, Listeria monocytogenes, and Enterobacter sakazakii analyses

C. perfringens has taken place in meat, vegetable, and other fillings, and products such as filled pasta, pastry in all of the criteria published since 2001. C. perfringens analysis was delisted from the bouillon tablet powders, soups in dried form, whipped cream, the other mixtures such as powder and tablets of gravies that appeared in the Notifications No. 2009/6 and 2009/68. This strain has been just involved in “not heat treated meat products” legally since 2011.

An increase in Listeriosis outbreaks have an increase in the fresh fruits-vegetables have been observed in recent years (12,13). While the L. monocytogenes analysis took place only in cheese, butter, ice cream, pudding, etc., soups consumed after being cooked, and both products, in the first published Notification No. 2001/19, it has been given place as the food safety criteria with the changes since 2009 in many foodstuffs such as milk products, meat products, pizza and flour based products, pies, and pastries (4,14,15).

E. sakazakii (renamed as Cronobacter sakazakii). Although E. sakazakii has been isolated from several foodstuffs, because of the risk of food groups to create the baby food, E. sakazakii analysis in the baby food and follow-on formula was made mandatory by the changes in the TFC. Baby formula and follow-on formula (including dietary foods for special medical purposes) have to be inspected for this strain since 2009 (4). Table 4 summarizes the criteria for C. perfringens, L. monocytogenes, and E. sakazakii from the beginning to the last form in TFC Microbiological Regulation.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>2001/19 product group</th>
<th>Official Gazette of Publication: 29.12.201128157-Product group</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. cereus</td>
<td>Fruit and flavored ice cream, grain flour, processed cereal products for breakfast,</td>
<td>As the criteria of food safety: dried infant formula (including dietary food for special medical purposes), infant formula and follow-on formula (including dietary food for special medical purposes), supplementary food for infant and little children (including dietary food for special medical purposes), spice, herb and/or mixtures of both of them (in powders, paste form, mixtures, etc.), all sorts of ready-to-eat (cooked) meat and vegetable meal, etc., all sorts of ready-to-eat (cooked) bakery products (pasta, all sorts of pastray, lahmacun, flatbread, pizza, Manti, etc.), food ready or unready-to-eat (in pathogen limits appendix)</td>
</tr>
<tr>
<td>E. coli O157:H7</td>
<td>(It was named as S. aureus) Milk powders, casein, caseinate, cheese, butter, plain and fruit/flavored ice cream, frozen or unfrozen ready-to-eat noodle, pizza, pastry, etc., products, pasta, pudding, etc., confectionery products, halva, vegetable soup consumed without being cooked and soup consumed after cooked, bouillon cubes, products with cocoa, gelatin, mayonnaise and dressings, ready-to-eat daily food and snacks</td>
<td>Minced meat, the mixtures of raw and prepared red meat, MSM (red meat and poultry), fermented sausage, etc., ready-to-eat - fruit and vegetable juices (pressed directly - unpasteurized-must be kept in refrigerated), raw and frozen or dried vegetables separately and mixed (entreating washed, chopped and packaged)</td>
</tr>
</tbody>
</table>
| Coagulase-positive Staphylococcus | As the criteria of food safety: Butter and spreadable milk products and plain butter, cream, milk powders and cream powders, powders mixtures for ice cream, whey powder, buttermilk powders and milk based products powders, casein and caseinate, cheese (all sorts of cheese except cream cheese) | Staphylococcus enterotoxin: Cream cheese and its products, all sorts of ready-to-eat (cooked) vegetables and meat food, etc., all sorts of ready-to-eat salad, charcuterie products, cold snacks, all sorts of ready-to-eat (cooked) bakery products (pasta, all sorts of pastray, lahmacun, flatbread, pizza, Manti, etc.), all sorts ready-to-eat (cooked) desserts such as pudding, mhlallebi, cream, asure, water pudding, etc.)  
As the criteria of production hygiene: Cheese made from raw milk, cheese made from milk processing under lower temperature than pasteurization and ripened and unripened cheese produced by milk heating pasteurization or higher pasteurization temperature or made from whey, milk powder and whey powders, unripened soft cheese processed by pasteurization or higher temperatures than pasteurization or whey (fresh cheese) |

MSM: Mechanically separated meat, S. aureus: Staphylococcus aureus

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Table 4. The legal regulation made by C. perfringens, L. monocytogenes, and E. sakazakii criteria

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>C. perfringens</td>
<td>Cheese, grain flour, processed cereal products for breakfast, ice cream, frozen and unfrozen ready to cook pizza, pastry, etc., products, coated/filled biscuit, wafer, vegetable and animal origin soup consumed uncooked, products with cocoa and chocolate, starch</td>
<td>(C. perfringens has been named as sulfite reducing anaerobic bacteria) As the criteria of food safety; not heat processed meat products (pastrami, etc.), pasta, mantı, etc., products filled with meat, vegetable and other fillers (baked), ready and unready-to-eat foods (in pathogen limits appendix)</td>
</tr>
<tr>
<td>L. monocytogenes</td>
<td>Cheese, butter, ice cream (plain, fruit, flavored), pudding, etc., soup consumed after cooking, beef broth products</td>
<td>As the criteria of food safety; cream (pasteurized), cream, cheese (all sorts of cheese except processed cheese), processed cheese and processed cheese products, ice cream and ice with milk, not heat processed meat products: fermented sausage, etc., and heat processed meat products (hot dog, etc.) pizza, dough and dough-based products (frozen and ready-to-cook) pies and cake, foods for special medical purposes, all sorts of salads ready-to-eat, charcuterie products and cold snacks, pressed directly unpasteurized ready-to-consume fruit and vegetable juice must be kept in refrigerated, washed, chopped, and pre-packed, separated or mixed raw vegetables and frozen or dried vegetables, processed bivalve mollusks, crustaceans, gastropods, cephalopods, fish, foods ready-to-consume (in pathogen limits appendix)</td>
</tr>
<tr>
<td>E. sakazakii</td>
<td>Not present</td>
<td>(E. sakazakii has been named as C. sakazakii) Baby formula and follow-on formula (including dietary foods for special medical purposes)</td>
</tr>
</tbody>
</table>

C. sakazakii: Cronobacter sakazakii, E. sakazakii: Enterobacter sakazakii, L. monocytogenes: Listeria monocytogenes

4.5. Histamine, and Vibrio species and sterility control analyses

Histamine analysis was first added to TFC Microbiological Criteria Regulation in the “Fishery products” group. Vibrio cholera and Vibrio parahaemolyticus (ready to consume fishery products bred/fished on in salty water) analysis was introduced into the list of pathogenic microorganism limits. Sterility control took place in the Notification No. 2009/68 in the Ultra-high temperature (UHT) milk (including fruit and aroma), pasteurized fruit and vegetable juices, their mixtures and syrups, and canned fruits and vegetables. With the regulation published in 2011, this analysis was totally removed (4).

In the inspections of food plants, samples are taken due to suspicions and microbiological control purposes, and either they are in compliance with the limits mentioned in the TFC Microbiological Criteria Regulations is detected, regarding the food safety and production hygiene conditions (1). Microbiological criteria provide substantial criteria that would help the actions and proceedings of the food processors according to the hygiene principles (4).

5. Discussion

Microbiological criteria give guidance on the acceptability of foodstuffs and their manufacturing processes. Preventative actions, such as the application of GHP and Good Manufacturing Practices, and the HACCP principles contribute to achieving food safety. Microbiological testing alone cannot guarantee the safety of a foodstuff tested, but these criteria provide objectives and reference points to assist food businesses and competent authorities in their activities to manage and monitor the safety of foodstuffs, respectively. It is preferable that food businesses use the microbiological criteria in the context of their food safety management systems based on HACCP principles. The food businesses should be able to ensure that foodstuffs meet the criteria and that manufacturing processes function in such a way that the criteria are met (16). It is considered that it would be useful to update the existing criteria, by means of making microbiological risk evaluation workshops, sharing detailed information and interactive studies in the national and international levels, and determining the legal criteria by means of evaluating the scientific study results in determining the microbiological threats together with the sample analysis results of the market inspections. It is considered that toxins and metabolites should be handled more largely, in compliance with the food structure as “Food Safety Criteria.”

6. Conclusion

Each risk parameter that appears in the regulations is in a quality of verdict, in terms of preventing the foodborne microbiologic threats and applying the legal sanctions. The needs and developments in the food technology and hygiene practices may require revision of the evaluations of existing threats and risks.

Conflict of Interests

Authors have no conflict of interest.

Acknowledgments

None.

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