Temporary increase of official controls at border control posts in the European Union: theoretical assessment of the measures laid down in Commission Implementing Regulation EU/2019/1793

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Abstract

This study assesses the effectiveness and efficiency of measures provided for by Commission Implementing Regulation (EU) 2019/1793 by determining the rate of consignments not complying with European Union legislation placed on the European market despite increased controls through the use of probability theory and Bayes' theorem methods. In addition, it takes into account different provisions for intensified official controls to improve performance. The study revealed that the effectiveness of measures provided, intended as a reduction in the rate of non-compliant consignments placed on the market, appeared limited despite a great effort in terms of performed official controls. This rate was always lower than the rate of the increased controls and closely linked to the test sensitivity and specificity, determined by the combination of sampling procedures with analytical methods. Furthermore, the efficiency, intended as the ratio between the number of analyses carried out and the number of non-compliant consignments found, was just related to the starting prevalence and sensitivity.

Instead, the provision for intensified official controls, based on additional checks carried out following each non-compliant result, was able to significantly reduce the rate of non-compliant consignments placed on the market.

In conclusion, this study showed that the protection level offered by the measures laid down might not be proportionate to the effort made. To improve effectiveness and efficiency, sampling procedures and analytical methods with high sensitivity and specificity are needed, aided by the availability of reliable information to identify subsets of consignments with a higher prevalence of non-compliance.

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Introduction

Regulation EU/2017/625 (European Parliament and Council of the European Union, 2017) stated, *inter alia*, that official controls (OCs) performed on animals and goods entering the European Union (EU) from third countries are of key importance and their frequency should adequately address the risks that animals and goods might pose, taking into account the operator's previous compliance history, the controls already performed on those animals and goods in the third country concerned, and the guarantees provided by that third country, which must comply with the requirements laid down in EU legislation. Thereafter, Commission Implementing Regulation (EU) 2019/2130 (CIR EU/2019/2130) (European Commission, 2019a) laid down detailed rules on the operations to be carried out during and after the documentary checks, identity checks, and physical checks.

Increased controls at the border control post (BCP) level are performed on certain goods where emerging or known risks justify it. In this case, when it is necessary, due to a known or emerging risk, or when a widespread serious non-compliance with the Union rules is suspected, the European Commission enforces a temporary increase of OCs at their entry into the EU, by means of implementing acts.

Within this purpose, the Commission Implementing Regulation

(EU) 2019/1793 (CIR EU/2019/1793) (European Commission, 2019b), as amended, established: i) the list of food and feed of non-animal origin from certain third countries subject to a temporary increase in OCs, ii) the rules on the frequency of identity checks and physical checks, including sampling and laboratory analyses, for the consignments, and iii) the rules on the methods to be used for sampling and laboratory analyses. According to Annex II paragraph 6 of CIR EU/2019/2130, with respect to consignments subject to measures provided for in the acts referred to in points (d), (e), and (f) of Article 47(1) of Regulation (EU) 2017/625, physical checks shall include laboratory tests and shall be carried out in such a way that it is not possible to predict whether any particular consignment will be subjected to such checks.

Data available on the Rapid Alert System for Food and Feed Window, as summarized in *Supplementary Table 1*, show the extent of non-compliant consignments detected at the BCP level, while no data are available on the number of physical checks actually carried out following the CIR EU/2019/1793.

These data show the detected non-compliant items, but for a proper assessment of the real effect of the provided measures, it is necessary to answer a simple question: what are we not seeing? What is the amount of non-compliant consignments placed on the EU market despite the adoption of those measures? This study, using combinatorics and statistical methods based on Bayes' theorem, aims: i) to assess the effectiveness and efficiency of a temporary increase in OCs, as laid down in the CIR EU/2019/1793, trying to evaluate the prevalence of non-compliant consignments *de facto* placed on the EU market; ii) to assess different provisions for increasing OCs based on the escalation of OCs frequency after each non-compliant result.

Materials and Methods

As above mentioned, CIR EU/2019/1793 focused on the frequency of carrying out physical checks, including sampling and laboratory analyses, as part of increased controls, in particular on a random basis and following the methods set out in Article 3.

Moreover, following Gerhardt (Gerhardt *et al.*, 1986), the result of any laboratory test is affected by and related to three main factors: sensitivity and specificity of the test and prevalence of non-compliance in the target population. Focusing on the laboratory test, it is possible to identify two different stages: the sampling procedures and the laboratory analysis. The sensitivity and specificity of lab tests are often well-known and considered in the assessment of the results. Sampling procedures also greatly affect the test results, as shown in a recent paper on sampling methods for detecting mercury levels in fish (Ciccarelli *et al.*, 2019). For this study, we will take into account the sensitivity and specificity of the combined system of sampling procedures and analytical methods.

Effectiveness and efficiency assessment

Based on these considerations, the set of consignments subject to increased frequency of OCs can be represented by Venn's diagram in Figure 1; given the set of consignments $G \in N$, Gn indicates the subset of compliant consignments and Gp the subset of non-compliant ones, so that $Gn \subseteq G$, $Gp \subseteq G$, $Gn \cap Gp = \varnothing$ and $Gn \cup Gp = G$; then the prevalence of non-compliant consignment can be expressed as $Prev_{init} = Gp/G$. Similarly, given the set of increased OCs $S \in N$, Sn indicates the subset of compliant checked consignments and Sp the subset of non-compliant ones so that $Sn \subseteq S$, $Sp \subseteq S$, $Sn \cap Sp = \varnothing$ and $Sn \cup Sp = S$. Assuming that the sensitivity (*sens*) and specificity (*spec*) of the combined system of sampling procedures and analytical methods are not 100%, it follows that $Sn = Tn \cup Fn$ and $Sp = Tp \cup Fp$ with $Tn \cap Fn = \varnothing$ and $Tp \cap Fp = \varnothing$, where Tn indicates the subset of true negative results, Tp the true positive ones, Fp the false positives results and Fn the false negative ones. Assuming a uniform and random distribution of non-compliant consignments, as implicitly assumed in the CIR EU/2019/1793, and according to Bayes' theorem, only four parameters are needed to predict the results of the increased OCs; indeed, it is known that: $S \times Prev_{init} = Tp + Fn$, $S \times (1 - Prev_{init}) = Fp + Tn$, $Sens$ and $Spec$ then: $\boldsymbol{Tp} = S \times Prev_{init} \times sens$; $\boldsymbol{Tn} = spec \times S \times (1 - Prev_{init})$; $\boldsymbol{Fn} = S \times Prev_{init} \times (1 - sens)$; and $\boldsymbol{Fp} = S \times (1 - Prev_{init}) \times (1 - spec)$.

Therefore, focusing on the performance of measures laid down in the CIR EU/2019/1793, the prevalence of non-compliant consignments placed on the market, despite the increased OCs, which represents a magnitude of the effectiveness of the provided

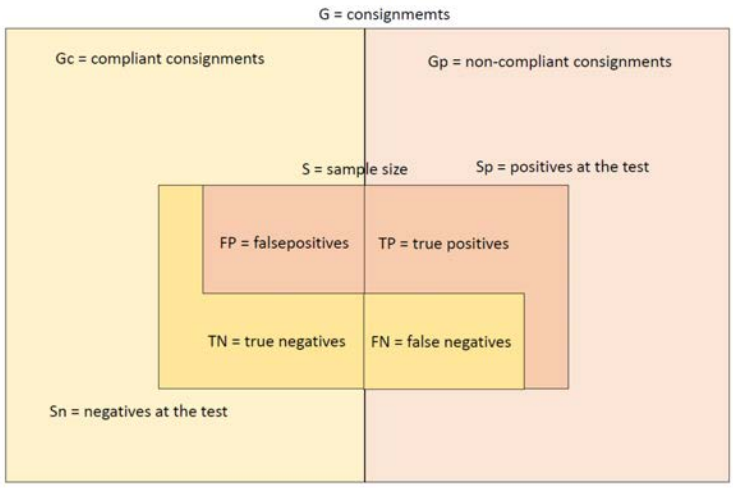

Figure 1. Venn's diagram of the set of consignments subject to increased frequency of official controls.

measures, can be expressed as [Eq. 1]:

$$prev_{market} = \frac{Gp_{market}}{G_{market}} = \frac{Gp-Tp}{G-Sp} = \frac{Gp-(S\times Prev_{init}\times sens)}{G-[(S\times Prev_{init}\times sens)+(S\times(1-Prev_{init})\times(1-spec))}$$

[Eq. 1]

where the number of consignments put on the market is $G_{market}=G-Sp$ and the number of non-compliant consignments placed on the market is $Gp_{market}=Gp-Tp$. The related efficiency can be expressed as the ratio between the found non-compliant consignments and the sample size, that is [Eq. 2]:

$$Efficiency = \frac{Tp}{S} = \frac{S\times Prev_{init}\times sens}{S} = Prev_{init} \times sens$$

[Eq. 2]

Taking into account the prevalence of non-compliant consignments and the sensitivity and specificity of the combined system of sampling procedures and analytical methods as system's variables, different scenarios were constructed: i) regarding the prevalence, four different scenarios, two of which are quite low, 0.01% and 0.05%, and two very high, 10% and 20%; ii) regarding the sensitivity and specificity, three scenarios of which the first, named {A}, representing a good performance, with 0.95% sensitivity and 0.99% specificity, and the rest representing poor performance, one named {B} with 0.80% sensitivity and 0.99% specificity, and the other, named {C}, with 0.95% sensitivity and 0.80% specificity.

Different provisions' assessment

To suggest how to improve the effectiveness of increased OC's frequency, different provisions were assessed, based on the hypothesis of increasing frequency after each non-compliant result, still assuming the uniform and random distribution of non-compliant consignments.

In this hypothesis, the combined sample size can be expressed as [Eq. 3]:

$$S_{(c)} = \sum_{i=1}^{n} S_1 + (S_2 + S_{pm1}) + \cdots + (S_n + S_{pm(n-1)})$$

[Eq. 3]

where $S_1 \ldots S_n$ are the sets of increased OCs, based on the basic frequency laid down by CIR EU/2019/1793, at time frame $T_{(m)1} \ldots T_{(m)n}$, whereas $S_{pm1} \ldots S_{pm(n-1)}$ are the sets of additional OCs calculated as the product of the *Sp* value of the previous time frame and the amplification factor *m*, that is the number of additional OCs after each non-compliant result; finally *n* is the number of considered time frames.

In this hypothesis, the prevalence of non-compliant consignments placed on the market, as per Eq. 1, is [Eqs. 4 and 5]:

$$prev_{market(c)} = \frac{Gp-(S_{(c)}\times Prev_{init}\times sens)}{G-[(S_{(c)}\times Prev_{init}\times sens)+(S_{(c)}\times(1-Prev_{init})\times(1-spec)]}$$

[Eq. 4]

Accordingly:

$$Efficiency_{(c)} = \frac{Tp}{S_{(c)}} = \frac{S_{(c)}\times Prev_{init}\times sens}{S_{(c)}} = Prev_{init} \times sens$$

[Eq. 5]

For the calculation, a weekly time frame was used, corresponding to the average time needed to obtain a lab result, for the duration of one year (52 weeks). Different sampling options were tested, following the above-mentioned scenarios, for two *m* values: 3 and 5.

Results and Discussion

Effectiveness and efficiency assessment

This study investigated the theoretical performance of the temporary increase in OCs at the BCP level, as laid down in CIR EU/2019/1793, in preventing the placing on the market of food and feed of non-animal origin non-compliant with EU Food Safety legislation, by assessing the prevalence of non-compliant consignments *de facto* placed on the EU market, despite the increased OCs. The effectiveness of these measures was studied using Eq. 1, and the assessment of the efficiency was based on Eq. 2. *Supplementary Table 2* summarizes the residual prevalence values of non-compliant consignments placed on the EU market despite the increase in OCs, following the speculated scenarios on the prevalence of non-compliant consignments and on sensitivity and specificity of the combined system of sampling procedures and analytical methods; the trend of the same data has been drawn in Figure 2.

The analysis of the scenarios pointed to the evident limited effectiveness of the foreseen measures, with a reduction rate of the original prevalence always lower than the corresponding rate of increase in OCs. When the starting prevalence is low, the reduction rate is poor, even with a high level of increased OCs. When the starting prevalence is high, the reduction rate, which stands for the non-compliant consignments found, is more prominent; nevertheless, the residual prevalence values might not be considered satisfactory.

Regarding the efficiency of the provided measures, looking at Eq. 2, it seems clear that it is independent of the number of OCs and strictly related to $Prev_{init}$ and sensitivity. Specifically, it will always be lower than the $Prev_{init}$ and can only match it in the exceptional case where the sensitivity is 100%.

Different provisions' assessment

This study also investigated the theoretical performance of temporarily intensified OCs based on additional OCs after each non-compliant result. In particular, a weekly time frame for a total of one year (52 weeks) was considered, and two *m* values were taken, where *m* represents the number of additional OCs after each non-compliant result.

Supplementary Table 3 summarizes the residual prevalence values of non-compliant consignments placed on the EU market, despite the intensified OCs, applying the amplification factor *m*=3 and following the constructed scenarios on prevalence, sensitivity, and specificity already used.

Similarly, *Supplementary Table 4* shows the residual prevalence values of non-compliant consignments placed on the EU market by applying the amplification factor *m*=5.

Figures 3 and 4 show data trends correlated to low or high starting prevalence values, respectively.

The data show increasing effectiveness of the provided measures when the *m* value increases, with a remarkable reduction rate of the starting prevalence of non-compliant consignments, mainly with lower specificity values or higher sensitivity values. This reduction rate is more evident for higher starting prevalence values. However, mainly when the specificity value is low, the provision of additional OCs could lead to checking and sampling all the consignments.

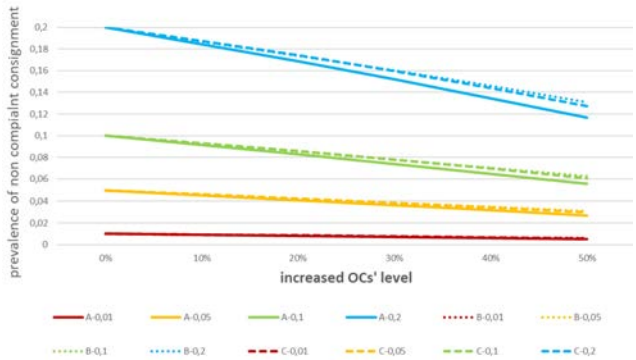

Figure 2. Trend of residual prevalence of non-compliant consignments placed on the European Union market despite the increased official controls (OCs) at the border control post level. Shown in the legend are the speculated starting prevalence (expressed with values from 0 to 1) and the performance of the sampling and analysis methods (A, sensitivity of 95% and specificity of 99%; B, sensitivity of 80% and specificity of 99%; C, sensitivity of 95% and specificity of 80%).

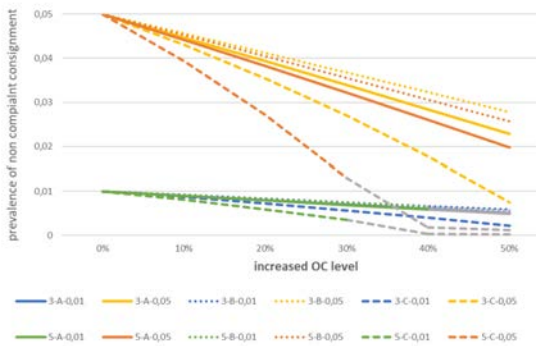

Figure 3. Trend of residual prevalence, in case of low starting prevalence, of non-compliant consignments placed on the European Union market despite the intensified official controls (OCs) at the border control post level with an increasing frequency (*m*=3) after each non-compliant result. The grey line corresponds to an appraised value as it involves sampling of all consignments presented. Shown in the legend are the speculated *m* value, the starting prevalence (expressed with values from 0 to 1), and the performance of the sampling and analysis methods (A, sensitivity of 95% and specificity of 99%; B, sensitivity of 80% and specificity of 99%; C, sensitivity of 95% and specificity of 80%).

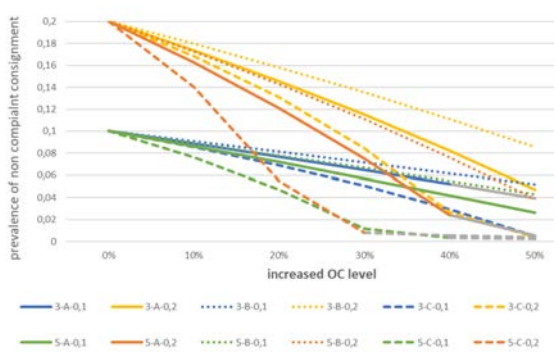

Figure 4. Trend of residual prevalence, in case of high starting prevalence, of non-compliant consignments placed on the European Union market despite the intensified official controls (OCs) at the border control post level with an increasing frequency (*m*=5) after each non-compliant result. The grey lines correspond to appraised values, as they involve sampling of all consignments presented. Shown in the legend are the speculated *m* value, the starting prevalence (expressed with values from 0 to 1) the performance of the sampling and analysis methods (A, sensitivity of 95% and specificity of 99%; B, sensitivity of 80% and specificity of 99%; C, sensitivity of 95% and specificity of 80%).

Regarding the efficiency of the provided measures, Eq. 5 is still independent of the number of OCs and strictly related to the prevalence and sensitivity.

Conclusions

This study assessed the effectiveness and efficiency of the temporary increase of OCs in preventing the placing on the market of non-compliant food and feed of non-animal origin, in line with EU food safety legislation, as laid down in CIR EU/2019/1793. For the same purpose, it also assessed different provisions of intensified OCs, based on the increasing of the OCs frequency after each non-compliant result.

By the use of combinatorics and Bayes' theorem and assuming the uniform and random distribution of non-compliant consignments, the results estimated the prevalence of non-compliant consignments actually placed on the EU market, despite the increased OCs frequency at the BCP level, and revealed the following.

The effectiveness of measures laid down in CIR EU/2019/1793 is weak and, despite a great effort in terms of OCs carried out (up to 50% of incoming consignments), produces limited results allowing a significant number of non-compliant consignments to be placed on the market when the starting prevalence is quite high: in all cases the reduction rate is lower than the rate of the increase in the OCs frequency.

The sensitivity and specificity of the test, both in terms of sampling procedures and laboratory analysis, are strictly and directly related to the effectiveness of the provided measures.

The efficiency, expressed as the ratio between the found non-compliant consignments and the OCs' number, is related only to the sensitivity of the test and the prevalence of non-compliant consignments: when the sensitivity value is 100%, the efficiency is equal to the prevalence.

When the distribution of non-compliant consignments is not uniform, for instance, due to the seasonal trend of a specific hazard, and when, through data collection and analysis, a subset of consignments with a higher prevalence of non-compliance can be reliably recognized, focusing the temporary increased OCs on that subset will allow for improvements on both the effectiveness and efficiency of the foreseen measures.

The assessment of alternative provisions for intensified OCs, based on the increasing frequency of three and five samples taken after each non-compliant result, highlighted a clear improvement in the effectiveness of the measures implemented, despite a significant increase in the OCs' number, mainly when the specificity value is low.

In this last case, the efficiency is related to the sensitivity of the test and the prevalence of non-compliant consignments.

In conclusion, the study showed that the level of protection offered to EU consumers by the measures laid down in CIR EU/2019/1793 might not be proportionate to the effort made. To improve the effectiveness and efficiency of these measures, sampling procedures and analytical methods with high sensitivity and specificity and/or availability of reliable information to identify subsets of consignments with a higher prevalence of non-compliance are needed.

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Online supplementary material:
Supplementary Table 1. Number of non-compliant consignments found at the EU BCPs level, from January 2020 to March 2024
Supplementary Table 2. Residual prevalence of non-compliant consignments placed on the European Union market despite the increased official controls at the border control post level following the CIR EU/2019/1793.
Supplementary Table 3. Residual prevalence of non-compliant consignments placed on the European Union market despite the intensified official controls at the border control post level with an amplification factor m=3, after each non-compliant result.
Supplementary Table 4. Residual prevalence of non-compliant consignments placed on the European Union market despite the intensified official controls at the border control post level with an amplification factor m=5, after each non-compliant result.