END OF THE DEROGATIONS TO REGULATION (EC) 853/2004 FOR COW'S MILK IN ITALY

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ABSTRACT

Derogations for somatic cell and total bacterial count limits had allowed non-compliant milk to be used for cheesemaking in Italy. Commercial and health considerations prompted a decision to implement a program to gradually repeal the derogations. In this study, we report the statistical evaluation of the situation in 2007-2008, the outcomes of the program to close the derogation and observations of its effects during its implementation from 2010-2013 in the Lombardy region. The introduction of a progressive decrease of the limit allowed regulators to minimize the negative impact on production levels by focusing on the management of the most non-compliant farms first.

- Keywords: cow milk, derogations, somatic cell count, total bacterial count -

INTRODUCTION

After the adoption of European regulations for food safety (Reg. EC 178/2002, 852-853-854/2004), Italian farmers were still able to sell cow's milk that was non-compliant in somatic cell count (SCC) and total bacterial count (TBC), indicators of presence of udder pathogens and insufficient hygiene during production and storage, respectively, because of the derogation of article 10 of the Regulation (EC) 853/2004.

Specifically the derogation allowed for cow's milk with geometric means exceeding the legal limits (400,000 cells/ml for SCC and 100,000 CFU/ml for TBC) to be used for the production of cheese with ripening periods of at least 60 days. This derogation was based on the knowledge that potential risks linked to high SCC and TBC can be significantly reduced or even eliminated during the production processes and ripening periods (Annex IV of the Reg. EC 854/2004). In fact, many stages of processing have antimicrobial effects including: the cooking of curd, the acidification of curd, the salting of cheese and the reduction of free water. However, over the years unfavorable opinions about the use of non-compliant milk have increased in Italy. Aged dairy products, like Grana Padano and Parmigiano Reggiano cheese, represent the uniqueness and tradition of Italian raw milk cheeses. Given that they are some of the most popular cheeses on the international market, is the use of the "worst" milk appropriate for the "best" cheeses of Italy?

It became clear that the presence of the derogation did not promote improvement in the quality of Italian milk. Furthermore, according to the principles of the Community Regulations, a derogation has to be considered "temporary" and contingent on specific issues. A derogation, if it affects food safety, must always provide a time limit or an exit strategy that will lead to conformity with the other nations. For these reasons Italy began a gradual process to repeal the derogation. The project was developed in 2008, after which it was communicated to the European Commission (notification number 134/2010) and it was formalized by the "Agreement between the Government, Regions and autonomous Provinces of 09 September 2010". The goals of this study were to conduct a preliminary evaluation of the problem based on data from 2005 to 2008, to create a plan to phase out the derogation and to evaluate the results of its application over 2 years, from January 2011 to June 2013, in the Lombardy region (an area responsible for more than 40% of the national milk production).

MATERIALS AND METHODS

The data come from the analysis of the milk quality payment system instituted in the Lombardy region. The system requires at least 2 samples per month from each farm. The samples are taken from farms by trained and qualified dairy industry operators. For statistical evaluation and calculation of the geometric mean we selected the farms with continuous production and active participation in the milk quality payment system during the 2-year study period (roughly 4600 farms out of 6,000 total active farms in the region). The majority of farms can be characterized by rearing Holstein Friesian (85%) or Brown Swiss (15%) cows in loose housing with cubicles, with milking parlor, fed with mixed ration of corn silage, hay and concentrate. On these farms the average herd size is 70 cows and the average milk yield is 9,400 kg per cow per year.

TBC was determined with Bactoscan FC and the SCC was obtained using Fossomatic 5000 (Foss, DK). For descriptive statistics (frequency distribution of farms' geometric means of SCC and TBC) the free "R" software environment was used.

RESULTS AND DISCUSSION

Analysis of compliance

The distribution of the farms' yearly SCC and TBC geometric means during the year 2008 are represented in Figures 1 and 2, respectively (5,200 farms). The "yearly" geometric means were calculated for each farm from 24 or more samples per year. From the figures it is evident that the SCC situation was more critical than that of TBC with respect to Regulation 853/2004 limits (BERTOCCHI *et* al., 2012), (BOLZONI *et* al., 2007).

In Table 1 an evaluation of the farms' SCC rolling geometric means from 2005 to 2007 is presented. The "rolling" geometric means were calculated over periods of 2 or 3 months for TBC and SCC, respectively. The data show that 44% of the farms were consistently under the SCC limit, while 29% of farms exceeded it one or more times but returned under the limit within the 3-months observation period; the remaining 27% of the farms were still non-compliant after the observation period. Further analysis of the last group of non-compliant farms (Figure 3) revealed that only a small fraction of these farms returned to compliance shortly after the 3 months of observation. Most of the farms spent a long time in non-compliance and even some farms never became compliant. These were the farms that were able to avoid compliance by commercializing their non-compliant milk in a geographic area where most of the milk is used for aged cheese.

The end of the derogation: potential effects

According to the abovementioned observations, it could be hypothesized that closure of the derogation would cause economic problems

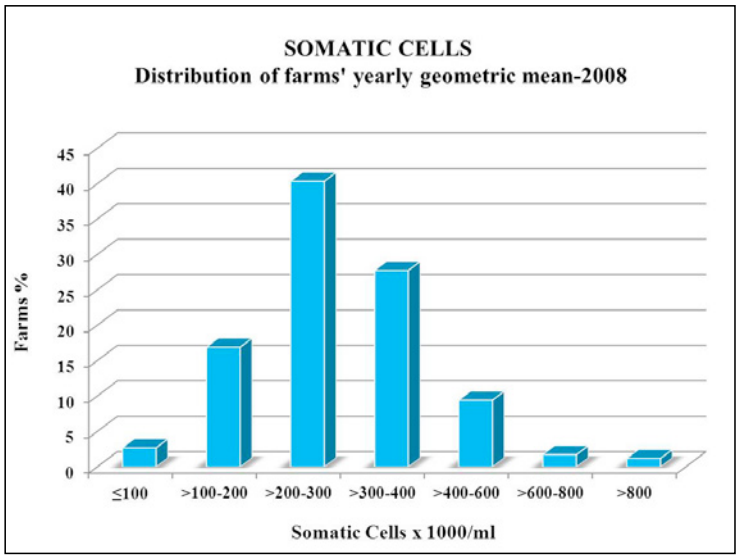

Fig. 1.

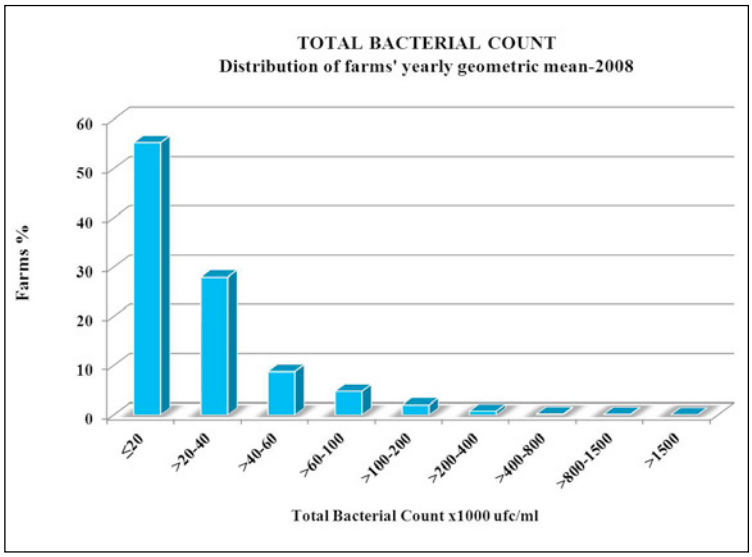

Fig. 2.

Table 1 - Somatic cell count compliance among 4,595 farms from 2005 to 2007.

Rolling geometric mean (cells/mL)	Farms (n)	Farms (%)
Always < 400,000	2,032	44%
> 400,000 with recuperation < 90 days	1,313	29%
> 400,000 without recuperation < 90 days	1,250	27%

for about 30% of the farms based on their SCC values and 4% of the farms based on their TBC values (data not shown). To explore these effects, we performed a statistical simulation on the 2008 data to quantify the effect of a gradual repeal of the derogation and its effects on farm production. The results of the simulation for SCC are presented in Table 2.

Program to repeal the derogation

A regional program was developed with a series of decreasing temporary limits. Given that controlling SCC levels is known to require both medium- and long- term actions, it was expected that some of the farmers would become proactive with control measures and improvements in order to reach compliance in time for the more restrictive future limits. The plan was approved by the Ministry of Health and then it was expanded into a national program with the "Agreement between the Government, Regions

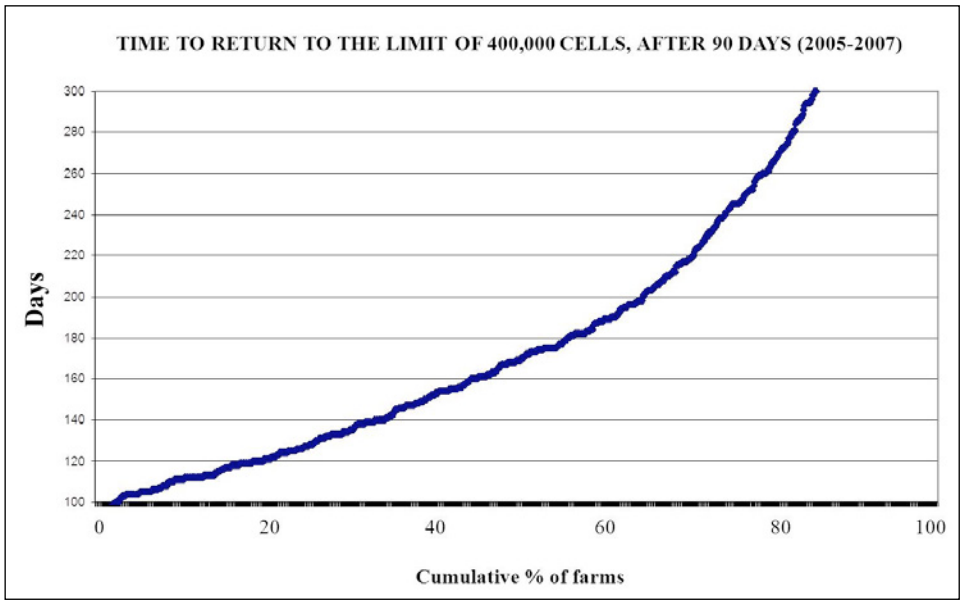

Fig. 3.

Table 2 - Geometric means of the compliance of 4,669 farms at different somatic cell count limits in 2008.

Somatic cell limit (cells/mL)	% of farms always under limit	% of farms over the limit with recuperation in 90 days	% of farms over the limit without recuperation in 90 days
700,000	89	8.4	2.7
600,000	83	12.1	4.6
500,000	73	19.6	7.7
400,000	50	32.1	18

Table 3 - Temporary limits for compliance during the program to close the derogation (geometric means calculated over periods of 2 or 3 months, respectively, for TBC and SCC).

PERIOD	Total Bacterial Count (Rolling GM calculated over 2 months)	Somatic Cell Count (Rolling GM calculated over 3 months)
January 2011 - June 2011	< 200,000	< 700,000
July 2011 - June 2012	< 100,000	< 600,000
July 2012 - June 2013	No derogation	< 500,000
From July 2013	No derogation	< 400,000

Abbreviation: GM, geometric mean.

and Autonomous Provinces". It banned the use of non-compliant milk for human consumption and set temporary limits for TBC and SCC as shown in Table 3. Currently milk with rolling geometric means > 400,000 for SCC or > 100,000 for TBC continues to be used in the production of cheeses with over 60 days of ripening.

Program application and results

Ten-year trends in SCC and TBC levels in the Lombardy region are shown in Figures 4 and 5, respectively. From these graphs it is possible to deduce a preliminary and general trend of decline in the two parameters. In particular, in fig-

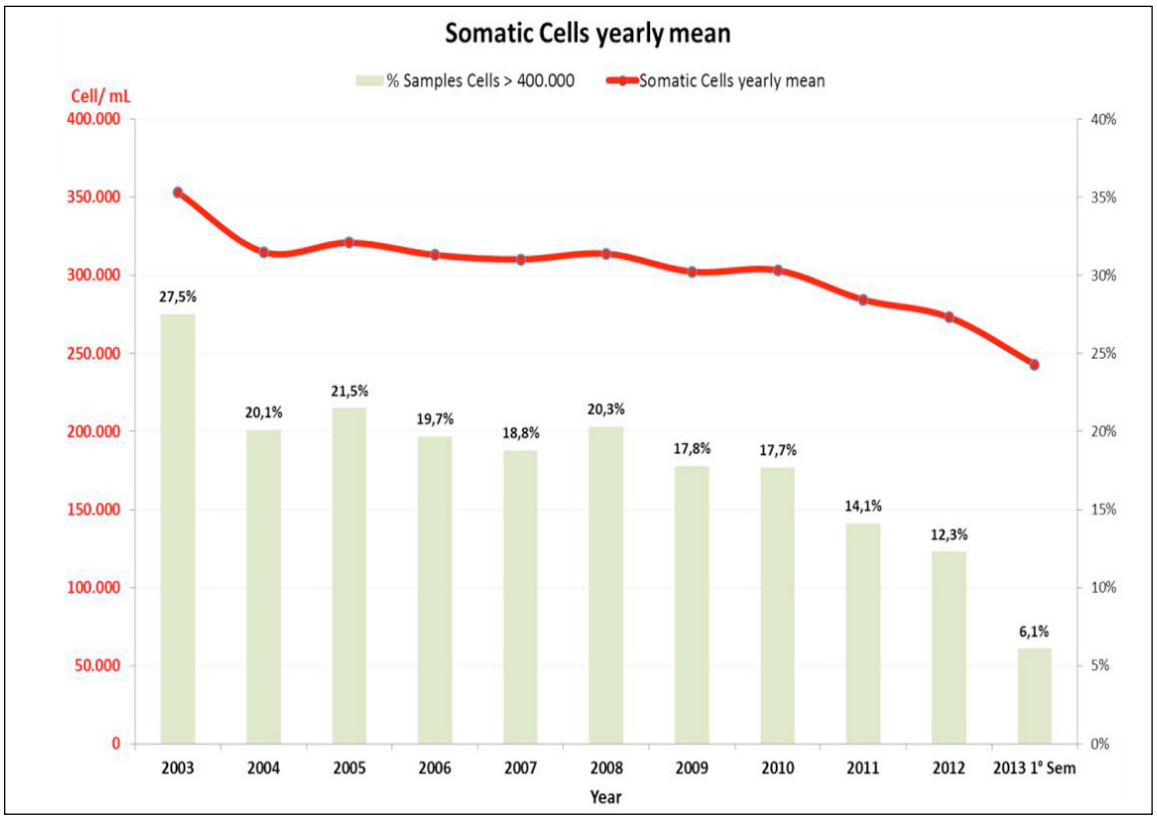

Fig. 4.

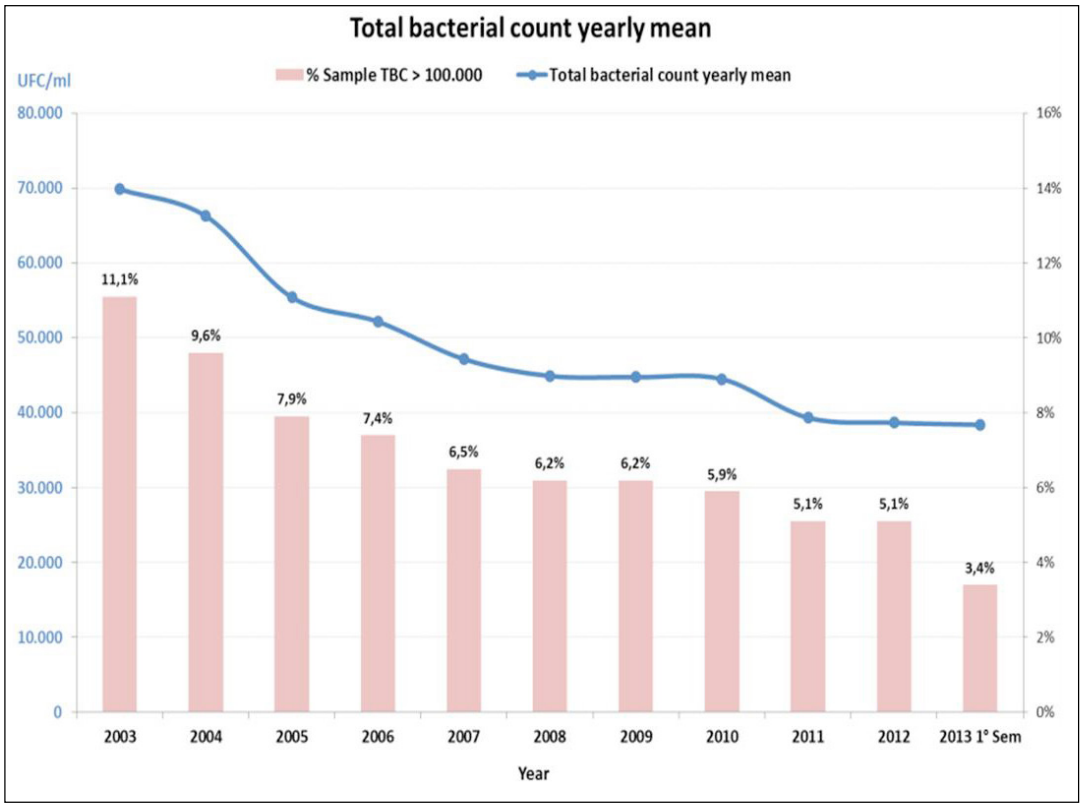

Fig. 5.

ure 5, the low percentage of samples over 100,000 UFC/ml (colored bars) and the low and decreasing value of the yearly regional mean (blue line), indirectly confirm the very low number of non-compliant farms in TBC during the last year. The number of samples used to generate the yearly means varies from a high of 165,000 in 2003 to a low of about 100,000 in 2013 which reflects the significant reduction in the number active farms in the region during this period.

Fig. 6 presents a specific assessment of the effect of the progressive application of the pro-

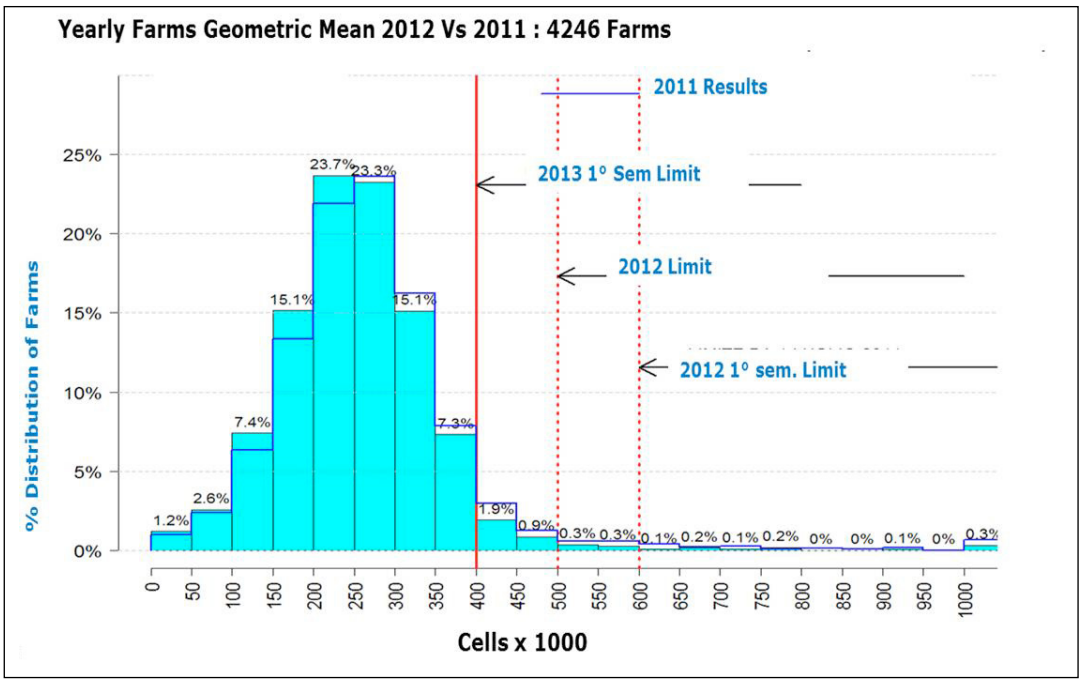

Fig. 6.

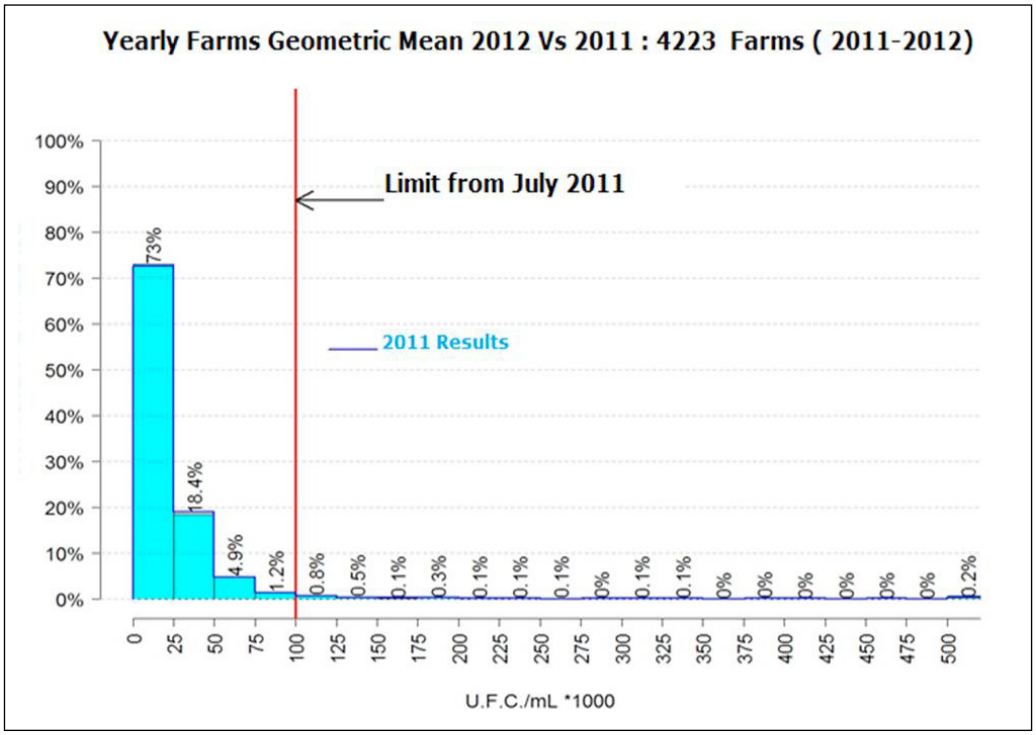

Fig. 7.

gram where the blue line indicates the distribution of the farms' geometric means in the first year (2011) while the blue bars indicate the situation in second year (2012). The difference between the two years is particularly evident in some areas (e.g. 200,000-250,000 SCC). It is interesting to note that there is a decrease in the percentage of farms presenting with 400,000-500,000 cells/ml in 2012 even though the limit was still set at 700,000-600,000 cells/ml. This again suggests that some farmers took preventive actions early with an eye to the more restrictive limits of 2013. Figure 7 presents the same comparison for the TBC. In this case, it is not possible to appreciate graphically the differences between the two years because of the minimal variations of the data across the board. One further analysis was performed on SCC to compare the first semester of 2010 (before the start of the program) and the first semester of 2013 and the data are presented in Figure 8; Figure 9 shows the same comparison between the first semesters of 2012 and 2013. It is evident that the percentage of geometric means with a lower SCC range increased over time while the higher SCC values decreased. For example, in Figure 8 the percentages of farms in the ranges of 300,000-350,000 and 350,000-400,000 cells/ml both decreased while the percentage of farms in the ranges of 100,000-150,000 and 150,000-200,000 cells/ml both increased almost equally. Even though the data come from thousands of different farms, the combination of these representations enabled us to notice a shift to the right in the distribution and through it the positive effects of the introduction of this progressive program. Its effects will be fully appreciated, of course, only in 2014 when the program will have been finished for over 6 months. However we still hypothesize that the impact on compliant productivity will be minimal due to the progressive shift of the majority of the farms to adopting long-term practices that should ensure their continued conformity within SCC limits (KELLY *et* al., 2009; NORMAN *et* al., 1995; SHUKKEN *et* al., 2003). The number of farms with TBC over the limit has already been negligible since 2011, likely because corrective actions against TBC can be effective in a very short time (KELLY *et* al., 2009).

CONCLUSIONS

The decision to repeal the derogations for SCC and TBC in raw milk was made for several reasons but particularly because of the need to stimulate improvements in the quality of milk and traditional dairy products. Statistical evaluation of the data from the previous years (2005-2007) suggested that a sudden closure of the derogations, especially for SCC, would create difficulties for farmers with downstream repercussions on the dairy industry as well as the Health Authority (regional veterinary service in Italy). The introduction of a progressive decrease of the limits allowed regulators to minimize these consequences and focus on the most non-compliant producers. At the same time, it allowed farmers to make improvements and preventive measures during the

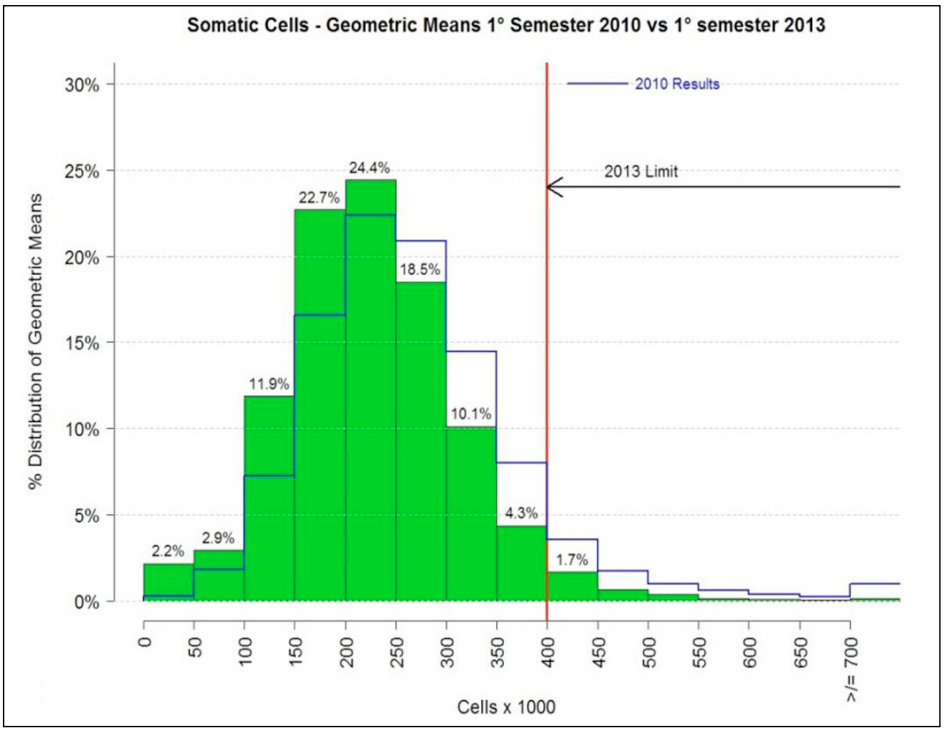

Fig. 8.

24-month program, without excessive conflict or serious effects on farm productivity.

The progressive reduction of the SCC limit also allowed the regional veterinary service to split the management of the non-compliant farms, giving priority to solving the most serious and significant problems first (starting from the first and highest limit of 700,000 cells/ml). The issue of non-compliance in TBC has been nearly resolved; since 2012 the cases of TBC non-compliance appear only occasionally and are often quickly resolved.

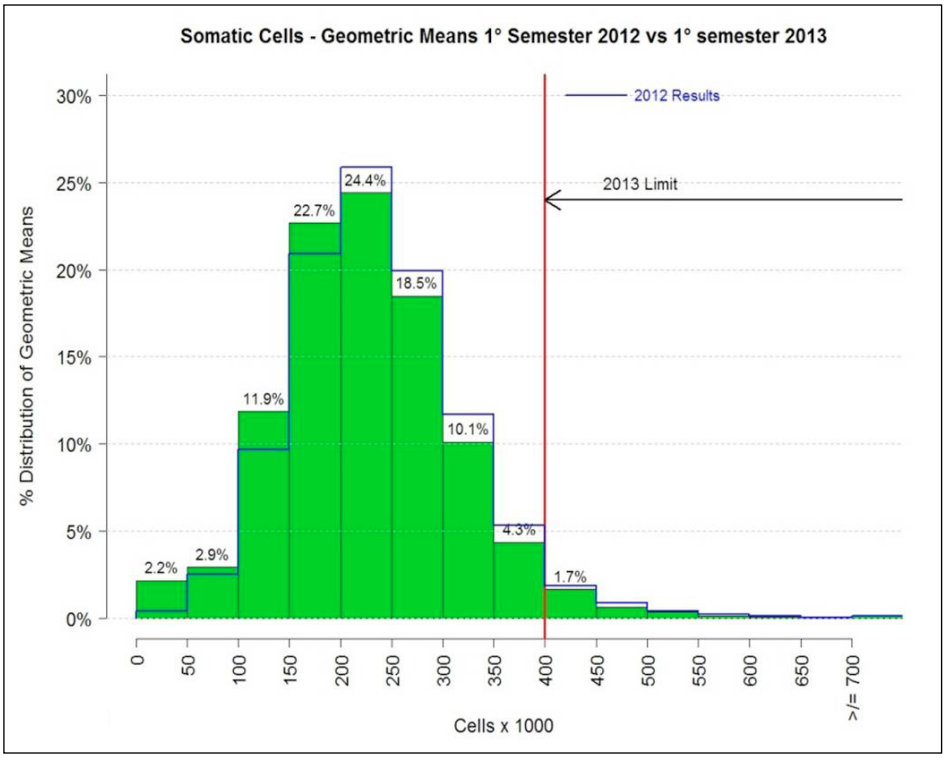

Fig. 9.

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