European Commission

Health Equity Pilot Project (HEPP)

Romania: Protection of breastfeeding for the health of infants and young children especially in vulnerable families

Case Study

Health

HEPP CASE STUDY

Title of Project/Policy
Romania: Protection of breastfeeding for the health of infants and young children especially in vulnerable families.

Project/Policy Reference [If applicable]
Law regulating the marketing of breastmilk substitutes – Notification Nr: 2016/554/RO (alternatively cited as 207/2016).

Country
Romania

Name of Organisation which initiated the law
The Romanian Parliament

Names of individuals
Relevant material has been obtained from national officials in 2016 and 2017 and supplemented using the findings from interviews with relevant respondents (see 'Authors and acknowledgements', page 10).

Type of case study
Situation report: Data analysis, published evaluations, interviews and correspondence with Romanian representatives.

Thematic/sector focus
Infant, young child and maternal nutrition, Health, Marketing

Date(s) of main actions

October 2015 Because of the serious risks associated with undermining breastfeeding the Romanian Parliament voted to control all forms of breastmilk substitute promotion[1].This control covers the sponsorship by breastmilk substitute manufacturers of Romanian facilities, and personnel providing maternity and new-born services. The Romanian law builds on the EU Directive/Regulation,[2] to further protect the health of young children up to 24 months, while still complying with the EU law. Breaches of these new Romanian controls would be a criminal offence and lead to substantial fines.

October 2016 The Romanian Ministry of Health notified the Technical Regulation Information System (TRIS system) of the EU of the new Romanian law and justifications for adopting such measures. (2016/554/RO (Romania).[3] Three Member States (Portugal, Sweden, United Kingdom) provided comments and two (Austria, France) issued detailed opinions.

Romanian law and justifications

Main Content: *The regulatory objective of the Law is to establish the legal framework for the marketing of breastmilk substitutes to ensure their correct use, as well as for the practice relating to the provision of accurate objective and consistent information to consumers. According to the explanatory notes, the Law is based on the principles of the International Code of Marketing of Breast-Milk Substitutes and aims to ensure an adequate and healthy diet for infants and young children.*

Brief Statement of Grounds: *Breastfeeding is the safest and best way to feed infants and young children. Breastmilk contains an ideal balance of nutrients along with other factors that protect against illness. The protection, promotion and support of breastfeeding helps ensure a safe and healthy diet for infants and young children and the correct use of breastmilk substitutes when these are necessary.*

February 2017 The Ministry of Economy notified the law to the Commission in accordance with art. 45 of EU Regulation 1169/2011 (Food Information to Consumers Regulation (FIC))[4] because the law contained specific elements for labelling. The waiting period required by FIC was extended to May 20, 2017

March 2017 At a Meeting of the Standing Committee on Plants, Animals, Food and Feed under Article 45 of EU Regulation 1169/2011 the Romanian Ministry of Health gave a presentation: *Law 207/2016 Marketing regulation for human milk replacers* stating that the law would have no impact on international trade. The Commission reiterated the lack of compliance with the notification procedure in the drafting stage and promised to take a formal position on the law after consulting other services and experts in health and nutrition claims. [5]

March 2017 the Romanian government proposed to postpone the law's implementation. It agreed to establish a working group of government and nongovernmental institutions together with food industry representatives to amend the Romanian law in order to ensure its compliance with EU laws.[5]

10th May 2017 The Romanian Law 207/2016 implementation was officially delayed until November 2019 (36 months after original publication). The rationale for the delay included the argument from the industry that the new Romanian Law imposes labelling changes which are laborious and lasting.[6]

11th of May 2017 was the initial date for entering into force of the Romanian Law 207/2016 on regulating the marketing of breastmilk substitutes.

Case Study Overview

The new legislation is seeking to protect breastfeeding as the most appropriate source of nutrition in the first 6 months. The new law will not only help reduce inequalities in maternal and young child health in Romania but may act as an exemplar for implementation by other EU Member States. Following the Romanian example could help governments achieve the global targets in breastfeeding for 2025, the Global strategy for Women's, Children's, and Adolescents' Health (2016–2030)[7]. It could also help Member States meet their obligations under the Convention on the Rights of the Child (CRC), the International Code of Marketing of Breast-Milk Substitutes and subsequent relevant Resolutions (the International Code) and the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW).

While a woman always has a sovereign right over her own body, the CRC recognises breastfeeding as a human right for both mother and child and calls on States to remove obstacles to breastfeeding. CRC General Comments Nos. 15 and 16 stress States' obligation to address the impact of business on children's rights and to *'implement and enforce internationally agreed standards'* to protect, promote and support breastfeeding through the implementation of the World Health Assembly Resolutions. They also set a direct obligation on companies to abide by the International Code '*in all contexts.*[8,9]

Background

Following the Romanian Revolution in 1989 and the collapse of the Soviet Union in 1991 multinational corporations, including those selling infant formulae, increased their marketing in the emerging markets of Central and Eastern Europe. During 1998-2004 the WHO and UNICEF, together with international NGOs, helped national authorities and civil society networks develop capacity to support breastfeeding and implement and monitor the International Code. For example, nine Romanian delegates from UNICEF, Government and civil society attended IBFAN Code Training courses in the International Code Documentation Centre, Penang between 1998 and 2004.

Romania joined the EU in 2007 and proceeded to harmonise its laws with EU legislation. In recognition of the need to protect child health, and in response to several calls from the European Parliament[10], some articles of

the International Code had been adopted into EU regulations by 1991. However, several key provisions and subsequent World Health Assembly Resolutions that clarified and strengthened the International Code, have not yet been implemented at EU level.

Romania is the seventh most populous member state of the European Union[11] and the Government estimates that around one quarter of the population is below the poverty line. Romania has the highest infant mortality rate in the EU and among the highest rates of small for gestational age infants. It also has the highest index of gender inequality. Romani people constitute one of Romania's largest minorities and according to the Council of Europe Estimate may be up to 8.63 % of the population in 2012.[12]

Increasing levels of breastfeeding is proven to be one of the most effective ways to ensure the highest attainable standard of health for infants especially in the first two years of life, but also right across the life course[13]. There is growing evidence that breastfeeding and appropriate early young child feeding helps reduce the risk of obesity and non-communicable diseases in adulthood, improves brain development and IQ and can lead to greater social mobility and transgenerational health benefits.[13,14,15] Breastfeeding also has a positive impact on maternal health, including reduced risk of breast and ovarian cancer and type 2 diabetes[16]. The risks of not breastfeeding are not limited to countries such as Romania, and are relevant to other EU countries, especially where low socio-economic mothers tend to breastfeed less.

Among the many obstacles to breastfeeding, such as inadequate paid maternity leave and lack of appropriate new-born services, the marketing of baby feeding products is recognised as a key barrier. Inappropriate marketing risks undermining governments' efforts to create an environment that protects families and supports sound decisions about infant and young child feeding.[17,18]

Based on the background above, the Romanian Government seek to implement a law to control the marketing of baby feeding products. Romanian data from between 2004 to 2011 show that most mothers breastfeed their infants on discharge from maternity facilities. In 2004, 37% were still exclusively breastfeeding at 6 months however this percentage seems to have reduced dramatically to only around 12% in 2011 - far below the Member States´ 2025 target of "at least 50% exclusive breastfeeding for first 6 months". [22] More data will be available from the National Reproductive Health Study in 2018.

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Baby feeding products marketing in Romania

Between 2008 and 2013 there was nearly a 5% annual growth rate for sales of milk formulae in Romania, worth USD 78.5 million annually, and by 2018 sales, including follow-up formulae, are projected to double[19].

Independent monitoring shows that health professionals play a key role in influencing product sales, and are often the target of sponsorship by the baby food industry.[20,18] International baby food companies operating in Romania have been found to offer to: train health professionals; pay expenses to attend international conferences; make donations to maternity hospitals when their formula is ordered; and provide nutritional supplements for pregnant and lactating mothers, as detailed in the baby milk action code monitoring report.[21] For example in 2011 a UNICEF supported survey showed that 65% of mothers of new-borns received free samples and mothers reported having direct contact with representatives from industry[22]

In Romania follow-up and toddler formulae are often cross-branded with infant formula. This can encourage parents to start feeding these products to infants in the first six months of life. Promotional claims and messaging, alongside materials and advice from health professionals, can suggest that products are more convenient and contain nutrients that are otherwise 'hard to get' from normal family food. Resource-poor families can lack understanding that this form of sophisticated marketing, can undermine confidence in breastfeeding and normal family foods that are often a safer, cheaper and healthier option for the whole family.

After an extensive literature review the European Food Safety Authority (EFSA) found a lack of evidence to support that follow-up formulae have any health benefit. EFSA warned that an unnecessary addition of nutrients can be burden a young child's metabolism:
"*From a nutritional point of view, the minimum contents of nutrients in infant and follow-on formula proposed by the Panel cover the nutritional needs of virtually all healthy infants born at term and there is no need to exceed these amounts in formulae, as nutrients which are not used or stored have to be excreted and this may put a burden on the infant's metabolism.*"[23]

Formula products targeting 6-36 month-old-children are expensive and potentially obesogenic. There is evidence that they can contain more sugar, be more expensive and encourage a preference for sweetened products[24,25,26]. Since 1986 the World Health Assembly has maintained that follow-up formulas are unnecessary.[27] (*WHA Resolution (WHA 39.28) adopted in 1986 3. REQUESTS the Director-General 3(2) to specifically direct the attention of Member States and other interested parties to the following:…(b) the practice being introduced in some countries of*

providing infants with specially formulated milks (so-called "follow-up milks") is not necessary.")

In addition there is concern that their marketing undermines breastfeeding and optimal complementary feeding among those Romanian infants most in need of breastfeeding.

In response to concern about the global market growth of follow-up formulae all EU Member States supported the adoption of a World Health Assembly Resolution in 2016. Its accompanying guidance clarifies that formulae targeting children 6-36 months are also covered by the International Code. Their promotion and cross branding with infant formula should be stopped and health professionals should not accept sponsorship from the companies who manufacture and distribute them.[28] The aim is to protect breastfeeding, while also helping to prevent obesity and noncommunicable diseases, and ensure that caregivers receive clear and accurate information.

Relevance

While from a market perspective Romanian Government initiatives to protect breastfeeding can be considered a constraint to market performance by baby food companies[20], this case study is a clear example that illustrates why health should take priority over trade. The evidence above underpins the World Health Assembly requirement since 1996 that national health professionals and maternity and new-born services should be free from commercial influence from those seeking to market baby food products during the 0-36 month period.[28]

All Member States have Human Rights obligations to protect children's health and regulate marketing, especially in populations with the least resources, where the risks to infant and child health are greater. The Romanian Government is, by prohibiting sponsorship within national health services, fulfilling its duty. Romania already attempts to create a better environment for breastfeeding by ensuring paid maternity legislation beyond that laid down by EU. Indeed, by following globally agreed recommendations Romania is more likely to achieve the global targets (see above) it has committed itself to achieve.

Interest from other Member States

Romania has more extreme poverty and social inequalities than most other Member States of the EU. However social inequalities and poverty are realities within all EU societies.

Although infant mortality and low birth weights may not be so prevalent in other EU countries compared with Romania, these other governments

have many other health problems associated with low socioeconomic status mothers such as: low levels of breastfeeding; high levels of teenage pregnancies (15-19yr); high prevalence of small or large for gestational age new-borns; and high prevalence of obesity in women of reproductive age.

Several countries in the WHO European region, such as Albania, Armenia, Azerbaijan, Georgia, Kosovo, Serbia, as well as EU Member States such as the UK, Malta, Luxembourg, Finland and Italy have made attempts to introduce legislation that goes further than the minimum required by EU legislation.[29]

In June 2017, the Council of Europe adopted *EU Council Conclusions to contribute towards halting the rise in Childhood Overweight and Obesity*[30]. This document stresses the importance of exclusive and continued breastfeeding and the need for protection from harmful marketing and undue commercial influence especially within the context of reducing health inequalities.

What makes this case study interesting?

Obesity in European children is strongly related to the socio-economic status of their parents: parents in lower socioeconomic groups are more likely to be overweight. Children of obese parents, or of parents with lower socio-economic status, are more likely to have poor eating habits and become overweight from birth. Also in most EU Member States, infants in lower socioeconomic families are less likely to be breastfed. For example even in Sweden, despite its good social welfare support system and a positive breastfeeding tradition, SES clearly has an impact on the breastfeeding duration[31].

Within the EU Action Plan on Childhood Obesity 2014-2020 breastfeeding is considered the best option for mothers and their new-borns who, if they are breastfed, appear to have a reduced risk of obesity in later life.

Sustainability

It is not just the lowest socioeconomic status women who suffer a disproportionate burden of obesity. A social gradient exists in most EU countries whereby each socioeconomic group is relatively more obese compared with the next socioeconomic group above them in the social spectrum. Moreover these inequities appear to be widening, thus creating a steeper gradient. Therefore government action to reduce this gradient requires strategies which combine both universal and targeted measures that offer universal protection to all while giving extra protection to those

with greatest need.

For example the existing EU inequities in the low prevalence of breastfeeding and high prevalence of obesity mean that their negative consequences disproportionately affect low socioeconomic families. These families are less likely to be upwardly socially mobile and more likely to be unemployed or suffer absenteeism from work due to ill health. Strengthening national legislation to curtail marketing of baby food products will give universal protection while helping those most susceptible to infant formula advertising, and will help protect their limited financial resources from inappropriate expenditure on formulae.

Once transferred into national law and assuming its implementation is monitored by independent bodies, a national law provides one of the most effective and sustainable measures to protect public health and reduce health inequalities.

Transferability to other countries /Transfer of experience

All EU countries have endorsed World Health Assembly Resolutions on infant and young child nutrition, and the target to achieve at least 50% of mothers exclusively breastfeeding till 6 months by 2025. However recent data suggest that only Slovakia and (49%) and Hungary (44%) are anywhere near achieving this. By following the Romanian example EU countries will have a better chance to achieve this target.

The largest gaps in high and low rates of breastfeeding between high and low socio-economic mothers are found in Ireland (63%), Malta (41%), UK (31%), Germany (28%), Netherlands (24%) and France (23%) difference. Of interest is that all these countries have also marked social gradients in the prevalence of obesity women of reproductive age, where an increased risk of obesity is transferred to next generations.

Member States are free to "give effect" to adopt national legislation related to the International CODE provided they are "justified and proportionate" and do not conflict with EU law. As mentioned above, several countries in the European region have gone further than the minimum required EU legislation. In 2014 Malta attempted to go beyond the basic EU standard but the process was derailed before Malta achieved a new national law. Assuming the Romanian law is successful this can be a positive sign to other Member States that their efforts will not be in vain.

Next steps / Recommendations

Policies to support mothers to maintain a healthy weight and protect breastfeeding are important to improve maternal and child health outcomes and reduce inequalities.

It is essential that the new elements of the Romanian law are retained and aligned as closely as possible with the *International Code of Marketing of Breast-milk Substitutes* and subsequent relevant Resolutions, to improve the health of the Romanian population, and assist the government to achieve international targets and goals.

Initial conclusion

The new Romanian law demonstrates the country's commitment to fulfilling its international obligations to protect children's rights to health and achieve global targets and goals. It provides an excellent example of the measures a Member State can take to further strengthen legislation in an area already regulated by the EU, to afford an even higher level of public health protection.

Sources of Funding for project

Romanian government, to protect and enhance breastfeeding.

References/ Studies/ Respondents studies

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[BACK COVER]