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**Protection of infant in the EU law and its
proportionality with regards to EU Charter
of Fundamental Rights**

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Introduction

Free trade is a building rock of European integration,¹ and it has been proven multiple times, that in order to be respected and followed in the policies of EU and Member States, it must go hand in hand with limitations suppressing its negative externalities.² Even though such limitations have various regulatory faces, the question might always be, whether this robust body is an adequate counterweight to the various dangers current market situation possesses. Moreover, this protection itself must reflect not only on different seriousness of potentially disruptive behaviours on the market (f. e. by differentiating grey and blacklists of unfair commercial practices), but also on different situation of specific consumer categories.

Infants are specific market stakeholders both in their needs and the way they behave (or rather do not behave). Both specificities call upon professionals from different areas of expertise to engage in discussion about proper regulation of products intended for infants' usage. This thesis wants to contribute to this still evolving discussion by providing legal point of view based on consistency in different layers of legal order and proportional balancing of interests, specifically in the topic of marketing of breast-milk substitutes. It is worth noting, that EU legal tools of infant protection have not yet been subjected to larger examination. The topic is even hotter as the discussions about reshaping marketing possibilities of manufacturers and distributors of breast-milk substitutes continue to occur³, currently also in Czech Republic, where a legislative

¹ Directorate-General for Communication. *Trade*. Online. Available at: https://european-union.europa.eu/priorities-and-actions/actions-topic/trade_en. [accessed on 2024-04-26].

² MULDER, Jotte. *Responsive Adjudication and the 'Social Legitimacy' of the Internal Market*. Online. European law journal: review of European law in context. 2016, vol. 22, issue 5, p. 597. Available at: <https://doi.org/10.1111/eulj.12205>. [accessed on 2024-04-25].

³ Both globally (World Health Organization. *New WHO report: European Region is still vulnerable to predatory marketing of breast-milk substitutes*. Online 10.6.2022. Available at: <https://www.who.int/europe/news/item/10-06-2022-new-who-report--european-region-is-still-vulnerable-to-predatory-marketing-of-breast-milk-substitutes>. [accessed on 2024-04-25].) and locally, f.e. in Ireland (Baby Milk Action. *Ireland called on to co-sponsor a Resolution on Digital Marketing*. Online. 21.3.2024. Available at: <https://www.babymilkaction.org/archives/42137>. [accessed on 2024-04-25].).

proposal is being prepared aiming to amend local regulation dealing with marketing practices linked to breast-milk substitutes⁴. The discussion is however often one-sided, prioritizing medical argumentation. Though, to understand the full picture and make just and rational decisions, all aspects must be considered, including legal substantiation.

Current protection of infants is pursued on multiple levels and this thesis aims to evaluate the level of their protection and consider the adequacy and legal conformity of this protection in the context of primary law, notably European Union Charter of Fundamental Rights. This thesis wants therefore to research what is current level of infants' protection and how current level of protection is achieving its goal – whether it truly respects the best interest of the child but also whether it stands the proportionality test when interfering with rights of other stakeholders. The thesis is divided into three chapters.

The first chapter assesses descriptively and analytically the valid general EU consumer protection law and its suitability to regulate commercial practices connected to products intended for infants' usage. For that, we must assess the qualification of infants as a market stakeholder and answer the question of their eligibility for consumer protection. We therefore analyse the EU law definition of consumer and special characteristics of particularly vulnerable consumer in EU law by interpreting the legal text and elaborate the understanding with interpretation provided by key EU bodies and jurisprudence. We then explore the possibilities of subsuming different situations of an infant and caregiver under the definition.

In the second chapter, we explore how the protection is achieved also by means of specific regulatory framework consisting of Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children,

⁴ Government of Czech Republic. *Government favoured interests of women and children: new measures limiting harmful effects of breast-milk substitutes*. Online. 27.9.2023. Available at: <https://vlada.gov.cz/cz/ppov/rovne-prilezitosti-zen-a-muzu/aktuality/vlada-uprednostnila-zajmy-zen-a-deti-nova-opatreni-k-omezeni-skodliveho-marketingu-nahrad-materskeho-mleka-208768/#>. [accessed on 2024-04-25].).

food for special medical purposes, and total diet replacement for weight control⁵ and of following Commission delegated regulations (EU) 2016/127⁶ and 2016/128⁷ further developing specific rules in the category of infant formulas and foods for special medical purposes intended for infants. To obtain full picture of the regulatory framework, we analyse not only the valid legislative acts, but we compare them with their roots in the form of preceding acts and international legal instruments, mainly World Health Organisation's International Code of Marketing of Breast-milk Substitutes adopted in 1981⁸. We do not stick solely to the text of the binding clauses, but we also explore the background of the acts and relations between them.

Once we understand the causes behind the current regulation *largo sensu*, we may examine the appropriateness of current level of protection by considering the impacts on important stakeholders, in this case the infants themselves, parents and caregivers⁹ of the infants and lastly manufacturers and distributors of breast-milk substitutes. The protective elements are trying to achieve certain level of welfare of infants by imposing several duties on producers and distributors of the formula products. Except of the legal description of the topic, the final aim of the thesis is to understand the ratio behind the regulation and evaluate its conformity with Charter of Fundamental Rights of the EU.

⁵ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181/35, 29.6.2013. (hereafter referred to as “**Regulation 609/2013**”)

⁶ Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding, OJ L 25/1, 2.2.2016. (hereafter referred to as “**BMS Regulation**” or “Delegated Regulation 2016/127”)

⁷ Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes, OJ L 25/30, 2.2.2016. (hereafter referred to as “**Infant FSMP Regulation**” or “Delegated Regulation 2016/128”)

⁸ Hereafter referred to as “**WHO Code**” or “the Code”

⁹ Even though the infant topic concerns parents mostly, the term of caregivers is wider and shall be understood in the thesis as including also parents.

Therefore, in the third chapter, we analyse firstly the scope of affected rights, guaranteed by the Charter: Article 24 of the Charter confirms the rights of the child, amongst which “*children shall have the right to such protection and care as is necessary for their well-being*” and the “*child's best interests must be a primary consideration*”. Article 35 calls for high level of health protection and Article 38 puts down that “*Union policies shall ensure a high level of consumer protection*”. Irreplaceable benefits of breast-milk for the infant are scientifically generally accepted¹⁰ and limiting advertising and marketing practices of formula manufacturers and distributors is trying to achieve this protection. We shall explore whether these instruments are indeed following proportionally the goal they have been adopted for.

Furthermore, as it always takes two for breastfeeding, we must consider other implications arising out of the regulation. The mother must invest time, energy and related missed opportunities to guarantee this precious source of nutrition. Limitation of information that the producers and distributors could spread might directly limit her freedom to receive information (Article 11) and indirectly, by limiting her proper knowledge about the possibilities, her freedom to engage in work, seek employment and to work (Article 15). In consequence the equality between men and women might be endangered (Article 23). Moreover, provision of adequate information, as part of consumer protection (Article 38) is not only important for mothers, but for any caregiver during his consumer decision making process.

We thus analyse also the nature of these fundamental rights and seek answer to the question, whether the pursue of infant's rights is properly balanced with not only those of manufacturers and distributors, but also those of the caregiver. For that we subject the important clauses of BMS Regulation to the test of proportionality. We adopt the same approach in relation to breast-milk substitutes manufacturers and distributors' freedom to

¹⁰ MARTIN, Camilia; LING, Pei-Ra; BLACKBURN, George. *Review of Infant Feeding: Key Features of Breast-milk and Infant Formula*. Online. Nutrients. 2016, vol. 8, issue 5, p. 1. Available at: <https://doi.org/10.3390/nu8050279>. [accessed on 2024-04-26].

conduct the business (Article 16) and freedom of speech (Article 11), which is involving marketing practices extensively. When analysing the nature of the fundamental rights at stake, we shall try to deepen the understanding of the rights by considering not only the text of the Charter itself, but more importantly the development of the interpretation, especially by looking into decisions of Court of Justice of European Union and opinions of jurisprudence.

From this analysis, we draw conclusion on whether the current regulation provides the best possible balance between the rights at stake and if it does not, we suggest the direction the regulator should take in order to achieve better balance between the interests. For this suggestion, we consider currently discussed modulations of regulation, from no regulation at all, through softer regulation than the current one, preserving status quo, tightening the regulation up to most severe regulation currently discussed (full implementation of the WHO Code). We shall evaluate these modes based on capability to achieve pursued protective goals and severity of infringement of fundamental rights.

In the end, we shall be able to critically evaluate whether there is a need or at least convenience to further develop or adjust current EU regulatory framework of the baby milk formula category in the area of allowed marketing practices, with special focus dedicated to marketing practices targeting public audience, by exploring various possibilities of the adjustment. If we come to conclusion, that the adjustment is needed, we lay down specific propositions for such adjustment.

1. Infants Under EU Consumer Protection

1.1. EU consumer protection law

Consumer protection is one of the protective legal institutes present in EU law. It is achieved on multiple levels and through various instruments¹¹. Core of the harmonised regulation consists of Unfair Commercial Practices Directive¹², Consumer Rights Directive¹³ and Unfair Contract Terms Directive¹⁴. Where general regulation is not enough, some specific situations requiring legislative intervention are then regulated, for instance travel and timeshare contracts¹⁵, defence of collective interests of consumers¹⁶ or cooperation between national authorities in cases of establishment of consumer and trader in different member states¹⁷.

The basis for this legislative framework can be found in Article 38 of the Charter of Fundamental Rights of European Union, which already provides the standard the EU policies in relation to consumers shall ensure – high level of protection. It is also reflected

¹¹ MAK, Vanessa. *Two levels, one standard? The multi-level regulation of consumer protection in Europe*. Online. In: European Consumer Protection: Theory and Practice. 2012, p. 21-29. Available at: <https://search.ebscohost.com/login.aspx?direct=true&db=e000xww&AN=443656&lang=cs&site=ehost-live>. [accessed on 2024-04-26].

¹² Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive'), OJ L 149/22, 11.6.2005. (hereafter referred to as „UCPD“)

¹³ Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council, OJ L 304/64, 22.11.2011. (hereafter referred to as „Consumer Rights Directive“)

¹⁴ Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts, OJ L 95/29, 21.4.1993.

¹⁵ Directive 2008/122/EC of the European Parliament and of the Council of 14 January 2009 on the protection of consumers in respect of certain aspects of timeshare, long-term holiday product, resale and exchange contracts, OJ L 33/10, 3.2.2009.

¹⁶ Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC, OJ L 409/1, 4.12.2020.

¹⁷ Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No 2006/2004, OJ L 345/1, 27.12.2017.

in other primary law – TFEU¹⁸ includes consumer protection among shared competencies in Article 4, section 2, letter f). The treaty then reaffirms the high level of protection in articles 114, section 3 and 169, section 1. Also secondary legislation often explicitly stipulates this goal.

A conceptual clash between consumer protection as a necessary barrier to free movement of goods, services, people and capital stands in behind of the regulatory framework. Single member state's legal provision in non-harmonised area, even if protecting consumer, might often surrender to the core value of market integration¹⁹. However, the harmonisation on EU level remains consistent with the concept of integration; even though limiting free trade, in the same time it enables it by setting more legally certain environment. Finally, by building single internal market, it also indirectly provides additional economic benefits for consumers through support of general prosperity. However, member state's national consumer protection rules going above the maximum harmonisation, when applied in EU secondary legislation, are not possible.

Even though the protection is not absolute²⁰ neither in harmonised legislation²¹, the interpretation follows extensive approach towards disputable situations, or in other words restrictive one when it comes to scope of the exceptions from consumer protection^{22,23}. In each case, however, when the protection comes into clash with other

¹⁸ Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326/47, 26.10.2012.

¹⁹ Case C-120/78, *Rewe v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)*, ECLI:EU:C:1979:42; However, it is still rarely possible for a member state to provide adequate substantiation of a serious interest in preserving the domestic rule, see cases C-382/87, *Buet and others v Ministère public*, ECLI:EU:C:1989:198, or C-244/06, *Dynamic Medien*, ECLI:EU:C:2008:85.

²⁰ WEATHERILL, Stephen. *Consumer protection under EU law 'is not absolute': yes, but be careful*. Online. European review of contract law: ERCL 2012, vol. 8, issue 2, p. 221-233. Available at: <https://doi.org/10.1515/ercl-2012-0221>. [accessed on 2023-11-11].

²¹ Cases C-412/06, *Hamilton*, ECLI:EU:C:2008:215, para. 39-40; C-166/11, *González Alonso*, ECLI:EU:C:2012:119, para. 27; C-215/08, *E. Friz*, ECLI:EU:C:2010:186, para. 44.

²² ŠMEJKAL, Václav. *Article 38. Consumer Protection*. In: Treaty on the Functioning of the European Union ; Treaty on European Union ; Charter of Fundamental Rights of EU: a commentary. Wolters Kluwer. 2022, p. 1588.

²³ Cases C-481/99, *Heininger*, ECLI:EU:C:2001:684, para. 31; C-122/10, *Ving Sverige*, ECLI:EU:C:2011:299, para. 29; C-166/11, *González Alonso*, para. 26; C-168/05, *Mostaza Claro*, ECLI:EU:C:2006:675.

objectives of primary law, these must be properly balanced, as “no provision of the Treaty obliges the Community legislature to adopt the highest level of protection...”²⁴.

1.1.1. Notion of consumer

For consumer protection rules to be applied in concrete situation, several conditions must be met in order to set a consumer-trader relationship. Among those the term of consumer has crucial importance. EU law in general²⁵ defines consumer as natural person²⁶, who in commercial practices (governed by specific legislation), is acting for purposes that are outside his trade, business, craft or profession²⁷. Next to real, flesh-and-blood consumer, who is subject to rights granted by the legislation, there stands also an abstract notion of average consumer (or, as specified by CJEU case-law, properly informed, reasonably observant and circumspect consumer²⁸), which serves for objective qualification of certain commercial activity as unfair in specific case of concrete consumer. It is the average consumer’s distorted economic behaviour, which sets the benchmark for an unfair practice to be classified as such.

The notion of consumer itself is based on general weakness or vulnerability²⁹ that he bears and which can take various forms as much as economic, social and cultural

²⁴ Case C-233/94, *Germany v Parliament and Council*, ECLI:EU:C:1997:231, para. 48.

²⁵ Primary law does not contain the definition of consumer. Only secondary legislation provides necessary characteristics (article 2, section (a) of UCPD; article 2, section 1 of Consumer Rights Directive), though the definition is not uniform among the acts (compare with SCHÜLLER, Bastian. *The definition of consumers in EU consumer law*. In: *European Consumer Protection: Theory and Practice*. 2012, p. 124. EBSCO. <https://search.ebscohost.com/login.aspx?direct=true&db=e000xww&AN=443656&lang=cs&site=ehost-live>. [accessed on 2024-04-26].).

²⁶ After stated *expressis verbis* in secondary law, the trait was even confirmed by CJEU in case C-542/99, *Idealservice MN RE*, ECLI:EU:C:2001:625, to encompass natural persons only.

²⁷ ŠMEJKAL, Václav. *Consumer Protection*. In: *European Union Law*. 3rd edition. Leges, 2021. Page 251.

²⁸ Case C-210/96, *Gut Springenheide and Tusky v. Oberkreisdirektor des Kreises Steinfurt*, ECLI:EU:C:1998:369 para 31.

²⁹ SZILÁGYI, Dániel. *Empowering Consumers: Towards a broader interpretation of vulnerable consumer concept in the European Union*. Online. Hungarian Journal of Legal Studies. 2022, vol 63, issue 3, p. 283- 285. Available at: <https://doi.org/10.1556/2052.2022.00337>. [accessed on 2024-04-26].).

development brings up new forms of business-consumer relationships³⁰. It entitles him for protection against business or professional party which is often being regarded as in stronger bargaining position³¹. However, even among the consumers, there is different need for protection based on the type of vulnerability as outlined by Reich³². General consumer protection law reflects this in granting special protection for such consumers by establishing another abstract construct – the category of particularly vulnerable consumers, who override average consumer test in situations where consumers are particularly vulnerable to a practice because of a specific reason.

Although, in concrete situations or relationships that deserve higher level of protection than general law can provide, EU regulator often choses special legislation based on specific subject-matter.³³ And even in this specific legislation, the concept of particular vulnerability might be reflected in granting additional attention to consumers in particular need.³⁴ Notably, some of these specific legislative acts are tackling dangers that free market possesses in relation to children's welfare and safety in order to reflect European Charter's Article 24, section 2. In July 2006, European Commission has already expressed the need to mainstream children's rights more efficiently into EU policies³⁵, when drafting both legislative and non-legislative actions³⁶. Finally, Lisbon treaty explicitly mentions protection of the rights of the child as one of its core goals in Article 3. Some secondary legislation had been adopted already in 20th century:

³⁰ FREEDMAN, Sidney. A short history of Consumer Policy in the EU. In: *Images of the Consumer in EU Law: legislation, free movement and competition law*. Oxford: Hart Publishing, 2016, p. 447, 461.

³¹ REICH, Norbert. Vulnerable Consumers in EU Law. In: *Images of the Consumer in EU Law: legislation, free movement and competition law*. Oxford: Hart Publishing, 2016, page 149.

³² *Ibidem*, p. 157.

³³ f.e. Directive 2008/48/EC, on credit agreements for consumers; Directive (EU) 2014/17, on credit agreements for consumers relating to residential immovable property; Directive (EU) 2018/1972 establishing the European Electronic Communications Code; Regulation (EU) 524/2013, on online disputes resolution for consumer disputes; Directive 2001/95/EC, on general product safety.

³⁴ see f.e. Article 3, section 3 of Directive 2009/73/EC, concerning common rules for the internal market in natural gas, Article 10 of Directive 2019/944 (EU) on common rules for the internal market for electricity or Article 10 of Regulation (EU) 536/2014, on clinical trials on medicinal products for human use.

³⁵ Communication from the Commission: *Towards an EU strategy on the Rights of the Child*, COM (2006) 367, 4.7.2006, para. II.3.

³⁶ *Ibidem*, para III.1, section. 3.

- former Toy Safety Directive³⁷,
- Young Workers Directive³⁸,
- Food Imitating Products Directive³⁹.

Some has been produced only recently:

- current Toys Safety Directive⁴⁰,
- Regulation 609/2013.

Still, the question whether EU regulator truly achieved the level of protection that primary law obliges, remains unanswered. Some might even conclude as Garde does, that: *“the EU institutions have so far failed to consider the best interest of the child as a primary consideration in EU consumer policy.”*⁴¹

1.1.2. Particularly vulnerable consumer

European Commission’s Guidance on the interpretation and application of the UCPD⁴² (UCPD Guidance) clarified the definition of particularly vulnerable consumer in the way that it enlarges the strict interpretation of UCPD’s definition. Particularly vulnerable consumer is, based on UCPD Guidance, not only a person who is particularly vulnerable based on his mental or physical infirmity, age or credulity (Article 5, section

³⁷ Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, OJ L 187/1, 16.7.1988.

³⁸ Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work, OJ L 216/12, 20.8.1994.

³⁹ Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers, OJ L 192/49, 11.7.1987.

⁴⁰ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170/1, 30.6.2009.

⁴¹ GARDE, Amandine. *The best interests of the child and EU consumer law and policy: a major gap between theory and practice*. Online. In: European Consumer Protection: Theory and Practice. 2012, p. 167. EBSCO. <https://search.ebscohost.com/login.aspx?direct=true&db=e000xww&AN=443656&lang=cs&site=ehost-live>. [accessed on 2024-04-26].

⁴² Commission Notice – Guidance on the interpretation and application of Directive 2005/29/EC of the European Parliament and of the Council concerning unfair business-to-consumer commercial practices in the internal market: Recital 2.6. OJ 2021/C 526/1, 29.12.2021.

3), but, taking into account Recital 19, it is a person who is particularly susceptible because of *specific characteristics* (such as mental or physical infirmity, age or credulity). UCPD's enumeration is therefore only demonstrative. We could analogically interpret the Recital 34 of the Consumer Rights Directive mentioning special consideration for "*consumers, who are particularly vulnerable because of their mental, physical or psychological infirmity, age or credulity*".

Therefore, this extensive interpretation of the definition includes not only groups like patients or children, but also for example pregnant women. However, the groups that fall under the definition still can be internally differentiated. Patients can have differently severe health problems and children's vulnerability changes with age. For instance, Ringold demonstrated, how perception of advertising evolves from kindergarteners up to adolescents, amongst whom the distrust towards advertising is generally dominant already,⁴³ as they appear "*marketplace literate*"⁴⁴ and "*understand the nature and function of advertising*"⁴⁵. Even though such position is academically challengeable⁴⁶, it sheds light on complexity of the topic. Changes in children's vulnerability do not even have to be always linear, meaning that older the children are, less protection they need. Nairn shows, how vulnerability of children changes based on the problem they are wrestling with (f.e. compensatory consumption in relation to low self-esteem has been proven to be the highest between age 13-15, compared to both younger and older children)⁴⁷.

⁴³ RINGOLD, Debra Jones. *Social criticisms of target marketing: Process or product?* Online. *American Behavioral Scientist*. 1995, vol. 38, issue 4, p. 585-586. Available at: <https://doi.org/10.1177/0002764295038004008>. [accessed on 2024-04-26].

⁴⁴ RINGOLD, Debra Jones. *Vulnerability in the Marketplace: Concepts, Caveats, and Possible Solutions*. Online. *Journal of Macromarketing*. 2005, vol. 25, issue 2, p. 207. Available at: <https://doi.org/10.1177/0276146705281094>. [accessed on 2024-04-26].

⁴⁵ *Ibidem*, p. 206.

⁴⁶ See for instance how vulnerable minors might be in relation to advertising in electronic games in NAIRN, Agnes, HANG, Haiming. *Advergaming. It's not child's play*. Online. Family and Parenting Institute, 2012. Available at: https://www.agnesnairn.co.uk/policy_reports/advergaming-its-not-childs-play.pdf. [accessed on 2024-04-26].

⁴⁷ NAIRN, Agnes. *Children as vulnerable consumers*. Online. In: *Consumer Vulnerability: Conditions, Context and Characteristics*. 2015, p. 79-88. Available at: <https://ebookcentral.proquest.com/lib/cuni/detail.action?docID=3570276>. [accessed on 2024-04-26].

Thus, even abovementioned adolescents could be in specific setting particularly vulnerable, if we extract them out of general children class and subject them to sophisticated marketing of a product or service their age group would be susceptible to. The better the specific group is targeted during legislative process, more tailor-made protection they can gain, even though striving for more zoomed definition brings up methodological obstacles (f.e. requirement of vast interdisciplinary approach)⁴⁸. Thus, only certain level of incidental particularly vulnerable consumers group targeting can be practically achieved, amongst which taking children as one category is the simplest, though most obsolete one.

Moreover, in some cases, person's legal capacity can be considerably diminished in relation with its qualification for "particularly vulnerable consumer" status. For example, a patient with very severe disease (f. e. after stroke) might be sometimes unable to express his will, even though he is still "consuming goods" and in this regard meets a trait of *private final consumer*⁴⁹, which could be defined as an "end user". However, it is more precise to understand the term economically as "final household"⁵⁰. The term of household is though problematic when speaking about legal capacity of a person. In cases of "non-acting consumer", commercial decisions are being done instead of him by a caregiver. Logically, commercial messaging is not in this situation targeting the patient, but the person taking care of him.

The same stands for new-borns and infants. Their safety and protection, particularly in these early years of life, are entirely the responsibility of a variety of "others"⁵¹. Even though they are by definition children⁵², it is appropriate to ask whether

⁴⁸ SPOTSWOOD, Fiona; NAIRN, Agnes. *Children as vulnerable consumers: a first conceptualisation*. Online. Journal of marketing management. 2016, vol. 32, issue 3-4, p. 222-223. Available at: <https://doi.org/10.1080/0267257X.2015.1107616>. [accessed on 2024-04-29].

⁴⁹ Case C-89/91, *Shearson Lehman Hutton v. TVB*, ECLI:EU:C:1993:15, para. 22.

⁵⁰ OECD. *Household consumption*. Online. National Accounts at a Glance 2013. OECD Publishing, 2013, p. 40. Available at: https://doi.org/10.1787/na_glance-2013-en. [accessed on 2024-04-26].

⁵¹ SPOTSWOOD, F.; NAIRN, A., *op. cit.*, p. 217.

⁵² Article 1 of UN Convention of the Rights of a Child is considered to provide general definition, even though EU law did not adopt any similar general age limit. (LAMONT, Ruth. *Article 24 – The Rights of the Child*. In: *The EU Charter of Fundamental Rights: a commentary*. Second edition. Hart

current legal framework is adequately protecting their interests when speaking about limitations imposed on trader's behaviour on the market. Except of that, we want to question the proportionality of this protection when taking into account externalities imposed on other stakeholders by this category regulation.

1.2. Consumer protection affecting infants

1.2.1. Infant as a market stakeholder

Products for infants' usage are designed to cover their specific needs. Their developing organism needs careful approach as wrong or inappropriate usage of some toys or foods might cause serious negative effect influencing them for whole life. First years of life are described and proven to be the most important years in the growth and brain development of the human, it is therefore crucial to pay attention to this stage of life⁵³. Not only first educative lessons and correct socialization of the child matter, but especially adequate nutrition brings necessary resources for the little one to develop. During this stage, a child's ability to grow can be affected by maternal and child's nutrition and health.⁵⁴ Appropriate early childhood development is even considered to be a fundamental right of every child⁵⁵.

However, in the first years of life, children are completely unable to obtain necessary nutrition by themselves – they are absolutely dependant on their caregivers.

Publishing, 2021, p. 713.). On the contrary, the upper age limit of “children” varies depending on the legal area of EU law, compare with STALFORD, Helen. *Children and the European Union : Rights, Welfare and Accountability*. Hart Publishing, 2012, p. 20-23. Available at: <https://search.ebscohost.com/login.aspx?direct=true&db=e000xww&AN=531169&lang=cs&site=ehost-live>. [accessed on 2024-05-06].

⁵³ UNICEF. *Early Childhood Development – UNICEF Vision for Every Child*. Online, UNICEF, 2023, p. 7. Available at: <https://www.unicef.org/media/145336/file/Early>. [accessed on 2024-04-26].

⁵⁴ LIKHAR Akanksha; PATIL Manoj S. *Importance of Maternal Nutrition in the First 1,000 Days of Life and Its Effects on Child Development: A Narrative Review*. Online. Cureus. 2022, vol. 14, issue 10. Available at: <https://doi.org/10.7759/cureus.30083>. [accessed on 2024-04-26].

⁵⁵ UNICEF, *op. cit.*, p. 7.

This seems to exclude them from consumer protection rules, as the definition of consumer presumes that the person is “acting”, even though children are, once able to act in legally binding way, considered not only consumers, but even particularly vulnerable ones and therefore enjoying higher level of protection⁵⁶. “Consumers are not defined by their nature, but by their acts and behaviour. The need for protection results from the specific situation and the specific behaviour involved in the sale of consumer goods”.⁵⁷ Thus, it is problematic to subsume under the term a person unable to express will, especially in case where the will is unsure at all due to possible lack of consciousness⁵⁸ (which some believe begins even prior to birth⁵⁹, while others consider different timings after birth⁶⁰; the consensus would supposedly depend on method of evaluation).

To match legal concept of free and serious will (as necessary preconditions to valid legal acting), it is even necessary to go beyond scientific opinions and combine those with philosophical approach, which questions the line and sets it even further into the childhood than the infant period⁶¹. It is not the aim of this work to set exact moment, from which we could consider a child acting, nor is intuitively imaginable that such a moment could be easily defined. It is rather necessary to approach the evaluation incidentally. It is however certain, that in case of infants, substantial doubts about seriousness of their intentions deprive them of consumer status. Even if we could see a

⁵⁶ ŠAJN, Nikolina. *Vulnerable Consumers*. Online. European Parliamentary Research Centre, 2021, p. 2. Available at: [https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690619/EPRS_BRI\(2021\)690619_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690619/EPRS_BRI(2021)690619_EN.pdf). [accessed on 2024-04-26].

⁵⁷ SCHÜLLER, B., *op. cit.*, p. 123.

⁵⁸ BAYNE, Tim. *When do humans become conscious – in the womb or after birth?* Online. In: BigThink.com 19.5.2023. Available at: <https://bigthink.com/the-well/human-consciousness-womb-after-birth/>. [accessed on 2023-12-02].

⁵⁹ BAYNE, Tim; FROHLICH Joel; CUSACK Rhodri; MOSER Julia; NACI Lorina. *Consciousness in the cradle: on the emergence of infant experience*. Online. Trends in Cognitive Sciences. 2023, Vol. 27, Issue 12, p. 1145-1146. Available at: <https://doi.org/10.1016/j.tics.2023.08.018>. [accessed on 2024-04-26].

⁶⁰ PERNER Josef; DIENES Zoltán. *Developmental aspects of consciousness: How much theory of mind do you need to be consciously aware?* Online. Consciousness and Cognition. 2003, vol. 12, issue 1, p. 63. Available at: [https://doi.org/10.1016/S1053-8100\(02\)00010-7](https://doi.org/10.1016/S1053-8100(02)00010-7). [accessed on 2024-04-26].

⁶¹ f.e. CARRUTHERS, Peter. *Human Creativity: Its Cognitive Basis, Its Evolution, and Its Connections with Childhood Pretence*. Online. The British Journal for the Philosophy of Science. 2002, vol. 53, issue 2, p. 243. Available at: <https://www.jstor.org/stable/3541765>. [accessed on 2024-04-26].

glance of will in the first year of their lives, levels would not be merely high enough to consider infant to understand a marketing concept, make a commercial decision or enter into a contract.

Even though UN Convention on the Rights of the Child stipulates the principle of emerging legal capacity, the line for consideration is usually drawn not earlier than 8 years⁶² of life. Arguably though, in consumer protection law, it is imaginable that the age for a child to be considered a consumer could lie even below⁶³. But when considering infants, it is the other person commercially acting on behalf of another – the caregiver, who is considered a consumer (if other characteristics of the consumer definition are met). This logical and theological conclusion cannot be corrected neither by BMS Regulation statement in Recital 5, that infants are vulnerable group of consumers. From systematic point of view, considering absence of such statement in previous subject-related instruments and nature of consumer term, the proclamation seems to be inaccurate.

Although, not only general consumer law does not provide for such “final receiving stakeholders” the direct protection, it also leads to lower consumer protection, if these would be considered particularly vulnerable because of their *specific situation* if they were able to express their will, as the person acting on their behalf will (often) not be classified as particularly vulnerable. Even if the caregiver was classified as such, the vulnerability would not be the same as the vulnerability of the infant and therefore it would not provide for the possibility to consider the commercial practice in view the infant.

⁶² see different approaches across jurisdictions f.e. in Ireland (ANDERSON Phil; DAVIDSON Gavin; DOHERTY Frances; HANNA Heather; HARPER Colin, et al. *Legal capacity, developmental capacity, and impaired mental capacity in children under 16: Neurodevelopment and the law in Northern Ireland*. Online. International Journal of Law and Psychiatry. 2023, vol. 87, International Journal of Law and Psychiatry. 2023, vol. 87, issue 101872, p. 3. Available at: <https://doi.org/10.1016/j.ijlp.2023.101872>. [accessed on 2024-04-26].), Czech Republic (FRINTA, Ondřej; FRINTOVÁ, Jana. *Part 7. §2 Natural Persons*. In: Substantive Civil Law 1. Second, updated edition. Wolters Kluwer, 2016, p. 222) or Germany (§ 106 of German Civil Code)

⁶³ BUREŠOVÁ, Jitka; POSPÍŠILOVÁ, Marie; UNGERMAN, Otakar; DĚDKOVÁ, Jaroslava; JURSOVÁ, Jitka; BERKI, Jan. *Online marketing communication targeting school age children*. Masaryk University, 2023.

Therefore, even though the infant is in its most vulnerable phase of life completely dependant on others, it does not gain any direct “additional protection” by means of general consumer law. To be precise, it is not (directly) protected at all. Since children as such are considered to be particularly vulnerable⁶⁴ and their vulnerability is reflected in multiple ways⁶⁵, how much more vulnerable are those children who not only cannot decide about their health, nutrition and development, but neither do they understand the dangers they face.

1.2.2. Caregiver as a consumer

Commercial practices linked to products made for infants aim at their parents or caregivers, not infants themselves. The bearer of consumer status is therefore the caregiver himself. Taking account of the conceptual reason behind whole consumer protection policy, it is the caregiver who is in “*weak position vis-à-vis the seller as regards his bargaining power and his level of knowledge*”.⁶⁶ It is the caregiver who is bargaining and using his knowledge respectively.

Parenting⁶⁷ in general is not a reason for gaining “particularly vulnerable consumer” status. Taking care of a child is not a qualified reason itself for considering a person particularly vulnerable, even though such life-status change has consequences on one’s well-being⁶⁸. *Ad absurdum*, if parenting was such a reason, as it brings a lot of mental uneasiness in the parent’s life (and thus could influence his susceptibility to

⁶⁴ KAPROU, Eleni. The legal definition of “vulnerable“ consumers in UCPD. Benefits and limitations of a focus on personal attributes. In: *Vulnerable Consumers and the Law*. 1st edition. Routledge, 2021, p. 58-59.

⁶⁵ GARDE, A., *op. cit.*, p. 187.

⁶⁶ Case C-240/98, *Océano Grupo Editorial and Salvat Editores*, ECLI:EU:C:2000:346, para 25.

⁶⁷ Where possible, parenting assessment is valid also for other caregivers, though the narrower term of a parent is more convenient to be used as it forms vast majority of cases and it is the term commonly used in relevant research.

⁶⁸ HIBBERT, Sally; PIACENTINI, Maria; HOGG, M. K. *Care leavers’ transitions to adulthood. Challenges to self when adapting to new consumer roles*. Online. In: Consumer Vulnerability: Conditions, Context and Characteristics. 2015, p. 123-125. Available at: <https://ebookcentral.proquest.com/lib/cuni/detail.action?docID=3570276>. [accessed on 2023-12-30].

specific commercial practice), almost everyone could be classified as a particularly vulnerable consumer, as dealing with stressful situations and periods together with doing responsible decisions comes hand in hand with living a human life. In addition, such broad understanding would hardly lead to meet the condition of clear identification (see below in the chapter). Although, it can happen that during life stage of a parent, one is or becomes particularly vulnerable consumer himself. Parent might become seriously physically impaired, or mother might be pregnant again⁶⁹. It is however unclear how their specific vulnerability (f. e. physical infirmity, minor parent, elderly caregiver, pregnant mother) would influence their vulnerability to the practice promoting infant product.

If we stick strictly to the condition of the particularly vulnerable consumer standard application, that the vulnerability must be caused by special characteristic (while the list is demonstrative⁷⁰), we could interpret, that in some cases, any kind of vulnerability, and thus vulnerability itself, could be considered a reason for (secondary) status of particularly vulnerable consumer. These cases might be important for example in relation to aforementioned “particularly vulnerable caregivers”. In other words, if a caregiver is due to his or her vulnerability, which might be of physiological nature, also psychologically disbalanced (thus susceptible based on strong emotional activity)⁷¹, that he or she might not be able to adequately take care of the child, it creates a secondary form of vulnerability in connection with decisions done on behalf of the child, even

⁶⁹ Reasons for considering pregnant women vulnerable are numerous and both of physical and psychological nature – pregnancy is accompanied by different physical problems and concern about child’s well-being and upcoming childbirth are quite stressful. (FRIANT-PERROT, Marine. *The Vulnerable Consumer in the UCPD and Other Provisions of EU Law*. In: The European unfair commercial practices directive: impact, enforcement strategies and national legal systems. Ashgate, 2014, p. 92)

⁷⁰ Recital 2.6. of UCPD Guidance.

⁷¹ See for example:

EDWARDS, Ben; CLARKE, Valerie. *The Psychological Impact of a Cancer Diagnosis on Families: The Influence of Family Functioning and Patients. Illness Characteristics on Depression and Anxiety*. Online. Psycho-Oncology. 2004, vol. 13, p. 567-570. Available at: <https://doi.org/10.1002/pon.773>. [accessed on 2024-04-26].; or
COMPANY-MORALES, Miguel; ZAFRA APARICI, Eva; CASADÓ, Lina; ALARCÓN MONTENEGRO, Cristina; ARREBOLA, Juan P. *Perception and Demands of Pregnant and Breastfeeding Women Regarding Their Role as Participants in Environmental Research Studies*. Online. *International journal of environmental research and public health*. 2021, vol. 18, issue 8, p. 1-3. Available at: <https://doi.org/10.3390/ijerph18084149>. [accessed on 2024-04-26].

though his primary condition (f.e. physical infirmity) would not be associated with commercial decisions done outside of the area directly influenced by his medical condition.

Teleologically however, category of particularly vulnerable consumer has been set forth in order to prevent commercial practices, that would not be considered unfair in perspective of an average consumer but would influence in an unfair way a disadvantage of certain specific category of consumers.⁷² Article 5, section 3 of UCPD states, that this vulnerable group of consumers must be clearly identifiable and the practice must distort the behaviour only of such group. As the concept of secondary vulnerability is based on indefinite objective preconditions granting the caregiver particularly vulnerable status (meaning basically any vulnerability) and also unclear subjective circumstances (specific experiencing of caregiver's vulnerability influencing his or her susceptibility to the commercial practice), in reality it would be problematic to consider "particularly vulnerable caregivers" as a clearly identifiable group of consumers.

In addition, we should not forget the condition of reasonable foreseeability of the impact of the commercial practice by the trader. Foreseeing any kind of vulnerable consumers to be distorted is impossible. Thus, for example, a chocolate producer cannot foresee which people having tough time might be distorted by his commercial practice and so the trader does not have to adapt his marketing strategies and communications accordingly. Even if we consider a producer of infant products, where it seems more appropriate to pose a question, whether the commercial practice might influence some particularly vulnerable caregivers in their decision-making, the group would usually not be clear enough so that the trader might adapt his commercial practices. In other words, it is hard to imagine the way the particularly vulnerable caregivers would be distorted when speaking about all kinds of particularly vulnerable caregivers.

⁷² Recital 18 of the UCPD Preamble

However, exceptions might exist. If we consider, that specifically breast-milk substitute products can differ in what specific needs they are trying to address (even though BMS Regulation requires them to cover all basic needs⁷³), there might be a situation, where trader intentionally targets (and therefore foresees) specific group of parents by messaging child's medical condition⁷⁴ with high probability of parent himself suffering by different, though related medical condition, which could make him particularly susceptible. For example, if we consider products for infant usage targeting caesarean section born babies (because of some special nutritional needs, when they cannot be breastfed), it goes hand in hand with mother delivering the baby in a way which might render her particularly vulnerable, as convalescence after such delivery requires additional attention⁷⁵, not excluding psychological difficulties, which might occur⁷⁶ (including higher risks of depression and anxiety⁷⁷). Same principle would apply to products addressing generally infant's allergy when supposing that the allergy is present in family.

In these cases, the threshold for stricter consideration of some commercial practices is met as all the preconditions of particular susceptibility, identifiability and foreseeability are present. Still the general problem with infant protection persists, as firstly, the parent's vulnerability, which could make mother susceptible for example to offers of post-labour therapies in case of c-section, would not necessarily apply to

⁷³ Article 2 and Annex I (and II) of BMS Regulation

⁷⁴ It must be borne in mind, that most of parents of infants with special medical condition requiring special form of nutrition cannot even be targeted, if the product concerned is an infant food for special medical purposes, whose public advertising is forbidden according to Infant FSMP Regulation.

⁷⁵ SANDALL, Jane; TRIBE, Rachel M.; AVERY, Lisa; MOLA, Glen; VISSER, Gerard H. A.; et al. *Short-term and long-term effects of caesarean section on the health of women and children*. Online. The Lancet. 2018, vol. 392, issue 10155, p. 1350-1352. Available at: https://www.researchgate.net/publication/328241536_Short-term_and_long-term_effects_of_caesarean_section_on_the_health_of_women_and_children. [accessed on 2024-04-27].

⁷⁶ BENTON, Madeleine; SALTER, Amy; TAPE, Nicole; et al. *Women's psychosocial outcomes following an emergency caesarean section: A systematic literature review*. Online. BMC Pregnancy Childbirth. 2019, vol. 19, no. 535. Available at: <https://doi.org/10.1186/s12884-019-2687-7>. [accessed on 2024-04-27].

⁷⁷ CLEMENT, Sarah. *Psychological aspects of caesarean section*. Online. Best Practice & Research Clinical Obstetrics & Gynaecology. 2001, vol. 15, issue 1, p. 111-112. Available at: <https://doi.org/10.1053/beog.2000.0152>. [accessed on 2024-04-27].

commercial practice linked to infant's specific nutritional needs. That would require incidental approach, as it is still possible, that a specific wording of an ad could unfortunately (or intentionally) invoke mother's feeling of lower capability to take care of the child⁷⁸ and therefore potentially distort her economic behaviour, which opens the door to particularly vulnerable consumer test, cause higher level of due care when engineering an ad and thus indirectly providing additional protection to the infant. Though such scenario seems to be exceptional.

Moreover, in general nor breast-milk substitutes, nor toys or complementary foods are marketed as suitable for very specific group of infants. Final question that must be posed, is therefore whether parenting an infant only is a condition for gaining particularly vulnerable consumer status, when parenting a child in general is not. Clearly identifiable physiological reasons could substantiate such submission of mother in the first 6 weeks after the delivery due to need of physiological recuperation across the body, notably the rehabilitation of pelvic floor influencing motoric capabilities⁷⁹. Both mother and newborn need to rest a lot and in more difficult situations (problems with breastfeeding, newborn's health problems, or only basic sleep deprivation), mother might be more open for impulsive commercial decisions, including purchase of medicaments, online courses, or baby formulas. After that, potential vulnerability causes mainly of psychological nature, though they meet at least identifiability and foreseeability conditions due to clear timeframe (0-12 months of age), in case of products targeting the children exactly in this period. In order to subsume whole infant parenting period under particularly vulnerable status, the link must be established between vulnerability of such parents and the susceptibility to related commercial practices. For this evaluation, we will consider two

⁷⁸ GAREL, Micheline; LELONG, Nathalie; KAMINSKI, Monique. *Follow-up study of psychological consequences of caesarean childbirth*. Online. Early Human Development. 1988, vol. 16, issues 2–3, p. 279. Available at: [https://doi.org/10.1016/0378-3782\(88\)90108-9](https://doi.org/10.1016/0378-3782(88)90108-9). [accessed on 2024-04-27].

⁷⁹ ZWINGER, Antonín; ŠKARDA, Martin. *Obstetrics*. 1. ed. Prague: Galén, 2004, 532 p.

major areas, that can lead to consumer's vulnerability, be it characteristics of the consumer (internal factor) and of the specific commercial environment (external factor)⁸⁰.

Parents are in this period, complementary to the lack of legal capacity of the infant, completely responsible for his well-being. Sudden and immense increase of responsibility reshapes one's world and brings about a lot of new emotions, both positive and negative⁸¹. Even though the parent is responsible for the child during whole childhood, the difficulty and extent (both quantitative and qualitative) is considerably higher compared to stages, when the child is being at least partially taken care of in specialized facility (kindergarten followed by school), can more or less speak about its needs and provides parents satisfaction by reaching life milestones and becoming independent. Nelson, Kushlev and Lyubomirsky sum up, that "*the evidence regarding child age clearly supports the conclusion, that parents of younger children experience lower well-being than parents of older children*".⁸² Though such conclusion is very vague when applied to specific question of vulnerability during infant parenting.

Firstly, when we take closer look, the evidence applied to our question is not that clear. Childbirth *in concreto* seems to for example boost levels of happiness.⁸³ Afterwards, levels of well-being significantly drop, which is attributed to challenging parenting in pre-school age, marital problems and sleep disturbances.⁸⁴ Though the exact timing, when the psychological well-being is reached (or at least considerably increased), varies based on area of life, where the well-being is observed. Thus, marital satisfaction might be lowest during whole period between age 0 and 2 of the child, whilst overall well-being continually declines until around the age of 5, when the child finally

⁸⁰ SZILÁGYI, D., *op. cit.*, p. 6-7.

⁸¹ NELSON, Katherine S.; KUSHLEV, Kostadin; LYUBOMIRSKY, Sonja. *The pains and pleasures of parenting: when, why, and how is parenthood associated with more or less well-being?* Online. Psychological Bulletin. 2014, vol. 140, issue 3, p. 875-876. Available at: <https://doi.org/10.1037/a0035444>. [accessed on 2024-04-27].

⁸² *Ibidem*, p. 880.

⁸³ CLARK, Andrew E.; DIENER, Ed; GEORGELLIS, Yannis; LUCAS, Richard E. *Lags and Leads in Life Satisfaction: A Test of the Baseline Hypothesis*. Online. The Economic Journal. 2008, vol. 118, issue 529, p. F234. Available at <https://www.jstor.org/stable/20108833>. [accessed on 2024-04-27].

⁸⁴ NELSON, S. K.; KUSHLEV, K.; LYUBOMIRSKY, S., *op. cit.*, p. 880.

achieves considerable level of autonomy.⁸⁵ Secondly and more importantly, low levels of well-being do not necessarily cause consumer to be particularly susceptible to commercial practices. If we consider for example causality with impulsiveness or compulsiveness of purchases, the evidence is mixed. Even though negative emotions in general seem to higher chances of impulsive shopping (namely depression or disappointment)⁸⁶, it also seems that specifically stress, fatigue, sadness or bad mood in general hamper impulsive buying (though the effort to relieve stress induces impulsive purchases). When it comes to compulsive purchases, such factors do not have significant effect.⁸⁷ In general, as the life stage of a parent consist of whole set of positive and negative emotions, amongst which some might fuel and some reduce impulsiveness in purchases, parent does not seem to be clearly identifiable particularly susceptible consumer in area of impulsive and compulsive shopping (as already assumed on page 14).

Still, more detailed causes of vulnerability must be examined. For example, whether the stage does not make parents particularly susceptible to specifically stage-related decisions about purchase of infant related products. Of all the negative emotions, anxiety and worry about the child's health and safety seem to be most prevalent.⁸⁸ These emotions have been recently well observed to cause both impulsive and compulsive buying during COVID-19 pandemics^{89,90}, show-casing recently proposed viewpoint by

⁸⁵ CLARK, Andrew E.; DIENER, Ed; GEORGELLIS, Yannis; LUCAS, Richard E., *op. cit.*, p. 234.

⁸⁶ LIU, Pei; HE, Jinglun; LI, Aimei. *Upward social comparison on social network sites and impulse buying: A moderated mediation model of negative affect and rumination*. Online. Computers in Human Behavior. 2019, vol. 96, p. 134. Available at: <https://doi.org/10.1016/j.chb.2019.02.003>. [accessed on 2024-04-27].

⁸⁷ GOGOI, Bidyut J. *Do impulsive buying influence compulsive buying?* Online. Academy of Marketing Studies Journal. 2020, vol. 24, issue 4, p. 1–15. Available at: <https://www.abacademies.org/articles/do-impulsive-buying-influence-compulsive-buying-9531.html>. [accessed on 2024-04-27].

⁸⁸ NELSON, S. K.; KUSHLEV, K.; LYUBOMIRSKY, S., *op. cit.*, p. 876.

⁸⁹ YU, Yohgjuan. *Effects of Negative Emotions and Cognitive Characteristics on Impulse Buying During COVID-19*. Online. Frontiers in Psychology. 2022, vol. 13, no. 848256. Available at: <https://doi.org/10.3389/fpsyg.2022.848256>. [accessed on 2024-04-27].

⁹⁰ JASPAL, Rusi; LOPES, Barbara; LOPES, Pedro; HUBERT, Marco. *Predicting social distancing and compulsive buying behaviours in response to COVID-19 in a United Kingdom sample*. Online. Cogent Psychology. 2020, vol. 7, issue 1, p. 12. Available at: <https://doi.org/10.1080/23311908.2020.1800924>. [accessed on 2024-04-27].

Badgaiyan et al., that “*individuals who experience emotional instability, anxiety, moodiness, and irritability would score high on impulsive tendency*”⁹¹. Even though parents often feel those emotions, the causes differ based on life stage of the child.⁹² Thus, fear itself could not be adequate reason for attribution of particularly vulnerable consumer status in all the child-related transactions due to lack of clear and sole identifiability (f.e. purchase of new family car based on an ad promoting such car). Although an ad promoting child seat should be considered from the viewpoint of particularly vulnerable consumers – abnormally worried parents, as the fear could be foreseen and would make them particularly susceptible.

Therefore, such submission would be very much product and/or commercial practise related. As demonstrated above, the trader should take into consideration the target group, only difference is, that instead of special condition of the parent (f.e. women after c-section) he should be aware, that parents in general might be particularly susceptible to commercial messages invoking health, safety or good child’s development (as anxiety and fear related topics). The fairness of such practices should therefore be examined from their perspective.

If we consider some of infant related products, the situation of foreseeability of vulnerability very much varies based on the category, as different preconditional feelings are present differently. Therefore, commercial practice marketing clothes would hardly play the same string as infant nutrition might. Breast-milk substitutes tackle area which is very sensitive, as health and nutrition are interconnected, as demonstrated before⁹³, and in first months of life, they play crucial role in child’s development. Parents also normally allocate more “nerves” to correct development of the child,⁹⁴ than to secondary needs

⁹¹ BADGAIYAN, Anantjyoti J.; VERMA, Anshul; DIXIT, Saumya. *Impulsive buying tendency: measuring important relationships with a new perspective and an indigenous scale*. Online. IIMB Management Review. 2016, vol. 28, issue 4, p. 194. Available at: <http://dx.doi.org/10.1016/j.iimb.2016.08.009>. [accessed on 2024-04-27].

⁹² NELSON, S. K.; KUSHLEV, K.; LYUBOMIRSKY, S., *op. cit.*, p. 876.

⁹³ LIKHAR A.; PATIL M. S., *op. cit.*

⁹⁴ MESIBOV, G. B.; SCHROEDER, C. S.; WESSON, L. *Parental Concerns About Their Children*. Online. *Journal of Paediatric Psychology*. 1977, vol. 2, issue 1, pages 13–17. Available at:

fulfilment, such as purchase of aesthetic clothes, taking cute photos or providing variety of toys, even though time allocation does not always have to copy allocation of worries. Marketing toys is somewhere in between as generally, the advertising in broader sense aims to promote mainly other characteristics than safety, though if it did so, it would be reasonable to apply higher reference standard too. Same might be applied when invoking support of development.

1.3. Adequacy of Consumer protection in relation to infants

Questionable is though effectiveness of attributing particularly vulnerable consumer status to the caregiver, as even “stricter fairness threshold” of the practice does not have to achieve desired result. We face two problems in this case. Firstly, caregiver does not usually possess enough information to be relatively sure about correctness of his or her actions when dealing with worries about child’s development, f.e. we are not sure whether parents are aware of all cognitive implications of correct inter-play with the child^{95,96}. When it comes to nutrition, the insufficiency of breast-milk might be perceived^{97,98} and breast-milk substitute can be even considered by mothers as a “true

<https://doi.org/10.1093/jpepsy/2.1.13>. [accessed on 2024-04-27]. and ALGARVIO, Susana; LEAL, Isabel. *PARENTAL CONCERNS DEFINITION: A SYSTEMATIC LITERATURE REVIEW*. Online. Psicologia, Saúde & Doença. 2016, vol. 17, issue 3, p. 424-425. <http://dx.doi.org/10.15309/16psd170310>. [accessed on 2024-04-27].

⁹⁵ DHAS, Brightlin N.; CHACKO, Shoba M.; DAVID SOLOMON, Vince S.; SRIRAM, Vimal. *Parents' awareness, knowledge, and experiences of play and its benefits in child development: A systematic review protocol*. Online PloS one. 2022, vol. 17, issue 9. Available at: <https://doi.org/10.1371/journal.pone.0274238>. [accessed on 2024-04-27].

⁹⁶ GINSBURG, Kenneth, R; the COMMITTEE ON COMMUNICATIONS; the COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH. *The Importance of Play in Promoting Healthy Child Development and Maintaining Strong Parent-Child Bonds*. Online. Paediatrics. 2007, vol. 119 issue 1, pages 184–185. Available at: <https://doi.org/10.1542/peds.2006-2697>. [accessed on 2024-04-27].

⁹⁷ HUANG, Yi; LIU, Yu; YU, Xiao-Yan; ZENG, Tie-Ying. *The rates and factors of perceived insufficient milk supply: A systematic review*. Online. Maternal & Child Nutrition, 2021, vol. 18, issue 1, p. 1. <https://doi.org/10.1111/mcn.13255>. [accessed on 2024-04-27].

⁹⁸ ROBERT, Emmanuelle; COPPIETERS, Yves; SWENNEN, Béatrice; DRAMAIX, Michèle. *The Reasons for Early Weaning, Perceived Insufficient Breast-milk, and Maternal Dissatisfaction: Comparative Studies in Two Belgian Regions*. Online. International scholarly research notices. 2014, no. 67856, p. 6. Available at: <https://doi.org/10.1155/2014/678564>. [accessed on 2024-04-27].

alternative”⁹⁹. One of the consequences of particularly vulnerable consumer benchmark might therefore be higher informative content of commercial messaging of infant products. However, we then run into second problem, being question of correct application of the information (parents seem to generally know how healthy diet should look like¹⁰⁰, but the knowledge itself seem not to lead to better child’s nutrition^{101,102}, while socio-economic factors seem to play crucial role¹⁰³) and bounded rational consumer - when deciding about complex topic of infant’s nutrition, more information might do none or even opposite effect on quality of caregivers’ decision.¹⁰⁴

Thus f.e., if caregivers was informed about the importance of every single ingredient, so that he might do more informed choice between competitive products, at the same time they might gain impression, that the BMS is almost as good as (or even better than) breast-milk, as it contains so much beneficial ingredients. Or the long list of health benefits could cause the caregiver not to read the benefits at all and decide between different products only based on length of such list. To sum-up, attributing caregivers of infants particularly vulnerable consumer status would be, where possible and logical, move in right direction, though the result of such submission would differ case-by-case

⁹⁹ BUNIK, Maya; SHOBE, Patricia; O’CONNOR, Mary E.; BEATY, Brenda; LANGENDOERFER, Sharon; CRANE Lori; KEMPE, Allison. *Are 2 Weeks of Daily Breastfeeding Support Insufficient to Overcome the Influences of Formula?*. Online. Academic Paediatrics. 2010, vol. 10, issue 1, p. 26. Available at: <https://doi.org/10.1016/j.acap.2009.09.014>. [accessed on 2024-04-27].

¹⁰⁰ HERNANDEZ, Raquel G; THOMPSON, Darcy A.; CHENG, Tina L.; SERWINT, Janet R. *Early-Childhood Obesity: How Do Low-Income Parents of Preschoolers Rank Known Risk Factors?* Online. Clinical Paediatrics. 2012, vol. 51, issue 7, p. 663-670. Available at: <https://doi.org/10.1177/0009922812440841>. [accessed on 2024-04-27].

¹⁰¹ ROMANOS-NANCLARES, Andrea; ZAZPE, Itziar; SANTIAGO, Susana; MARÍN, Lucía; RICO-CAMPÀ, Anaïs; MARTÍN-CALVO, Nerea. *Influence of Parental Healthy-Eating Attitudes and Nutritional Knowledge on Nutritional Adequacy and Diet Quality among Preschoolers: The SENDO Project*. Online. Nutrients. 2018, vol. 10, no. 1875, p 12. Available at: <https://doi.org/10.3390/nu10121875>. [accessed on 2024-04-27].

¹⁰² STRAUGHAN, Paulin T.; XU, Chengwei. *Parents’ Knowledge, Attitudes, and Practices of Childhood Obesity in Singapore*. Online. SAGE Open. 2022, vol. 12, issue 4, p. 8. Available at: <https://doi.org/10.1177/21582440221144436>. [accessed on 2024-04-27].

¹⁰³ DE ROSSO, Sofia; DUCROT, Pauline; CHABANET, Claire; NICKLAUS, Sophie; SCHWARTZ, Camille. *Increasing Parental Knowledge About Child Feeding: Evaluation of the Effect of Public Health Policy Communication Media in France*. Online. Frontiers in public health. 2022, vol. 10, no. 782620, p. 2. Available at: <https://doi.org/10.3389/fpubh.2022.782620>. [accessed on 2024-04-27].

¹⁰⁴ SCHÜLLER, B., *op. cit.*, p. 130-132.

based on concrete product and commercial practice in question, not guaranteeing truly higher indirect level of protection for infants.

Currently, we unfortunately lack judicial decisions of CJEU that would apply particularly vulnerable consumer standard in situations, where there is need to go to further details and examine the situation of consumers more in depth and context. Consensus is mainly present on application of such standard in relation to commercial practices distorting economical behaviour of larger, easily definable, often endogenous vulnerable classes¹⁰⁵ (f.e. commercial practices targeting children or elderly in general)¹⁰⁶, without consideration of “even more particularly” vulnerable sub-groups or “more vulnerable particular sub-groups” based on special causes of their vulnerability^{107,108} (specific market, special behavioural characteristics...¹⁰⁹).

Even though few more detail-oriented decisions have been already rendered too, they did not specify exactly the concept of particularly vulnerable consumer *per se* and only provided possible clues for understanding the term. One of the first, and in the same time specifically precisising aspect of vulnerability, was the case *Buet*, where door-to-door consumers were considered particularly vulnerable to educational materials¹¹⁰ (it must be

¹⁰⁵ WADDINGTON, Lisa. *Reflections on the Protection of „Vulnerable“ Consumers under EU Law*. Online. Maastricht Faculty of Law Working Paper. 2013, issue 2, p. 23, citing *Report on strategy for strengthening the rights of vulnerable consumers* (2011/2272(INI)), 8.5.2012, Committee on the Internal Market and Consumer Protection, Rapporteur: Maria Irigoyen Pérez. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2532904 . [accessed on 2024-04-28].

¹⁰⁶ WILHELMSSON, T. *The informed consumer v the Vulnerable Consumer in European Unfair Commercial Practices Law – „A comment“*. In: *The Yearbook of Consumer Law*. Ashgate publishing, 2007, p. 211 – 218.

¹⁰⁷ SZILÁGYI, D., *op. cit.*, p. 5-7, 13-14.

¹⁰⁸ HOWELLS, Geraint; TWIGG-FLESNER, Christian; WILHELMSSON, Thomas. *Rethinking EU Consumer Law*. Online. 1st edition. Routledge, 2017. Available at: <https://doi.org/10.4324/9781315164830> . [accessed on 2024-04-28].

¹⁰⁹ European Commission. *Executive Summary – Consumer vulnerability across key markets in the European Union*. 2016, p. 49-52. Available at: https://commission.europa.eu/system/files/2018-04/consumers-approved-report_en.pdf . [accessed on 2024-05-05].

Summary of this more targeted approach is well expressed in TNS Opinion & Social: *Special Eurobarometer 342: Consumer Empowerment. Report*. Online. 2011, p. 7. Available at: <https://europa.eu/eurobarometer/surveys/detail/768> . [accessed on 2024-04-28].: „The extent of vulnerability of an individual consumer depends on the interaction between the consumer’s individual combination of characteristics on the one hand and marketing practices on the other.“

¹¹⁰ Case C-382/87, *Buet and others v Ministère public*, para. 13.

noted, that the core question was consideration of national provision in absence of total harmonization during that time and simultaneous preference of minimum harmonization¹¹¹). Similar context (preservation of national provision) was present in case *A-Punkt Schmuckhandel*¹¹², though the decisive factor was not the consumer group but the specific sales environment. In both cases the national provisions were justified by an objective of general interest (protection of sort of vulnerable consumers) which prevailed over single market integration. Their importance lies mainly in demonstrating, that in assessing the amount of protection needed, situational approach is necessary. Once again in case *DKV Belgium SA*¹¹³, though already in harmonised context, the financial sector's sensitivity was reason to qualify the restriction as pursuing the objective of general interest. In case *Citroën Belux NV*¹¹⁴, the combination both of financial sector's complexity and combined offer's specificities were taken into account when justifying need for adoption of national measures to provide high level of consumer protection. In second tobacco advertising case *Germany v Parliament and Council*¹¹⁵, CJEU interestingly defined tobacco users as vulnerable consumers, based on addictiveness of tobacco and subsequent susceptibility.¹¹⁶ However, the classification did not grant these consumers some special rights or protection, but legitimised hard regulatory restrictions aiming at ensuring high level of health protection, as requested by primary law.

Moreover, Court of First Instance has also demonstrated will to narrow the examined consumers' group where appropriate, though the situations in stake were only dealing with framing of "average consumer" and therefore not narrowing the consumer test based on vulnerability: In joined cases *DigiFilm*¹¹⁷ the factors such as advertising in one or more Member States and the requirement of a particular language served to extract

¹¹¹ WADDINGTON, L., *op. cit.*, p. 14.

¹¹² Case C-441/04, *A-Punkt Schmuckhandel*, ECLI:EU:C:2006:141, para. 29.

¹¹³ Case C-577/11, *DKV Belgium*, ECLI:EU:C:2013:146, para. 41.

¹¹⁴ Case C-265/12, *Citroën Belux*, ECLI:EU:C:2013:498, para 39.

¹¹⁵ Case C-547/14, *Philip Morris*, ECLI:EU:C:2016:325.

¹¹⁶ *Ibidem*, para. 144, 159-160.

¹¹⁷ Joined cases T-178/03 and T-179/03, *CeWe Color v OHIM (DigiFilm)*, ECLI:EU:T:2005:303, para. 28.

relevant consumer group. In case *NLCollection*¹¹⁸ even product-based framing was considered, while the case concerned the clothes industry. Though, if we take into account the case of *Biker Miles*¹¹⁹, for such framing, the distinction based on target group of consumers would not be sufficient, if product is being (or might be) reasonably purchased also by consumer outside of target audience, as it is not adequately distinguished.

Calls for higher protection of some vulnerable consumers are nowadays when caught in legislation, then only partially by providing special protection for such groups directly in legislative acts regulating certain commercial environment¹²⁰. Benefit of this approach is clarity, which provides higher level of legal certainty. Even though adequacy of such special regulation might be questioned, it must not be forgotten, that even if a consumer, protected by special provisions granting for example broader rights of information, becomes victim of a commercial practice, that the regulation forgot or chose not to include in its scope, still the particularly vulnerable consumer standard might be applied. Though, such interpretation and application is not yet adopted nor ruled out in judicial practice.

All being said, if not any, only indirect, though probably rare, surplus protection might come from general EU consumer protection law with regards to infants (through consideration of the caregivers' susceptibility to certain commercial practice), even though they can be materially, rather than legally, considered particularly vulnerable. As demonstrated above, particularly vulnerable consumer test would logically be applied in relation to caregivers who are themselves particularly vulnerable in connection to infant's condition invoking foreseeability (f.e. breast-milk substitutes targeting c-section born babies) or exploiting specific parental conditions (BMS products or educational toys advertisings playing the string of worry of correct child's development and health). Application of such submission of caregiver under particularly vulnerable consumer class

¹¹⁸ Case T-171/03, *New Look v OHMI - Naulover (NLCollection)*, ECLI:EU:T:2004:293, para. 43.

¹¹⁹ Case T-385/03, *Miles International v OHMI - Biker Miles (Biker Miles)*, ECLI:EU:T:2005:276, para. 36.

¹²⁰ see footnote no. 32.

is though so far questionable, as we do not have enough judicial evidence supporting such approach combined with difficulties when proving meeting the conditions of particular vulnerability on case-by-case basis.¹²¹

In situation, where general protective elements of EU legislation, even though designed with clear goal to respond to dangers of free market, are unable to do it adequately, it is necessary to accompany general consumer protection law with special legislation dealing with subject-matter that normally escapes the scope of existing provisions. As we observed, the special needs of infants and partial inability of the caregiver to take rational decisions in the topic most related to infant – its nutrition, it seems appropriate to address the issue by means of aforementioned special regulation. Fortunately, European regulator has already done so, however, whether he did his job properly, must be brought under microscope.

¹²¹ Case C-649/17, *Amazon EU*, ECLI:EU:C:2019:576, para. 45-47.

2. Specific regulatory protection of infants

“EU obligations to respect fundamental rights, including children’s rights, implies not only general duty to abstain from acts violating these rights, but also to take them into account wherever relevant in the conduct of its own policies under the various legal base of the Treaties.”¹²² “Fundamental rights, thus, should be seen, as an integral part of all public policy making and implementation, not something that is separated off in a policy or institutional ghetto.”¹²³

When examining EU legal acts directly protecting the infant, the frequent presence of highly exact norms might be observed. Such trait is typical for evidence-based restrictions in which relatively high level of scientific substantiation plays role, notably the technical specifications, allowed quantities of some ingredients or total ban in case of complete unacceptance of some components. Such approach might be found in considerable extent in sectors of food and agriculture, product safety, medicines, chemicals, environment and others, with main goal of preventing damage to human or animal health, property, or environment by eliminating risks coming from extensive contact with some materials or their usage in products or processes^{124,125}. Scientific substantiation is in fact key element legitimising the extent of restriction, even though the situation in scientific community might be multi-polar and final decision is only a

¹²² Communication from the Commission: *Towards an EU strategy on the Rights of the Child*, *op. cit.*, para. I.3.

¹²³ GARDE, A., *op. cit.*, p. 180, citing C. McCrudden. *Mainstreaming Equality in the Governance of Northern Ireland*. Online. Fordham International Law Journal. 1999, vol. 22, issue 4, p. 1699.

Available at:

https://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?params=/context/ilj/article/1634/&path_info=22FordhamIntlLJ1696_281998_1999_29.pdf. [accessed on 2024-04-29].

¹²⁴ Communication from the Commission: *Towards a comprehensive European Union framework on endocrine disruptors*, COM (2018) 734 final, 7 November 2018, p. 9.

¹²⁵ Communication from the Commission: *Chemicals Strategy for Sustainability Towards a Toxic-Free Environment*, COM (2020) 667 final, 14 October 2020, p. 1-2.

consensus achieved by concrete empowered authority taking into account also other aspects (sociocultural, economic, ethical...) ¹²⁶.

Reason behind the specific protection of infants is logical – as it could not have been adequately reached via general consumer protection (or product safety rules, as described below) only, due to all necessary application of robust scientific knowledge (which is hard to execute on case by case basis ¹²⁷), hard submission of infants experiences under consumer protection provisions or these provisions capturing only generally inadmissible commercial practices, such as misleading and aggressive practices, without adequate consideration of infant's vulnerability, a significant call for stricter and more exact regulation made several regulations born on EU level. Taking into account infant's daily activities, two major areas where regulation is necessary, might be recognised: product safety and nutrition.

Product safety on general level is pursued by General Product Safety Directive ¹²⁸. “Safe product” is in Article 2 defined as *“any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons”*. A pattern similar to consumer protection legislation might be observed: criterion of foreseeable usage of a product is widening the scope of stricter “normal usage”. When looking at general definition of a “product” in the same article, condition of “usage by a consumer” links the product safety with consumer protection too - as the directive does not contain

¹²⁶ GUÉGEN, Daniel; MARISSSEN, Vicky. *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?* Online. Bruges Political Research Papers. 2022, vol. 88, p. 5-7, 26-27. Available at: https://www.coleurope.eu/sites/default/files/research-paper/wp88%20Marisen_Guegen.pdf. [accessed on 2024-04-29].

¹²⁷ POSNER, Richard. *Regulation (Agencies) versus Litigation (Courts): an Analytical Framework*. Online. In: *Regulation vs. Litigation: Perspectives from Economics and Law*. University of Chicago Press, 2009, p. 14-15. Available at: <http://www.nber.org/chapters/c11956>. [accessed on 2024-04-29].

¹²⁸ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 011/4, 15.1.2002. (hereafter referred to as “GPSD”)

its own definition of consumer, application of the general one present in consumer law seems necessary¹²⁹. In addition, between the elements that must be taken into account when considering the appropriateness of the risk, there are “*categories of consumers at risk when using the product, in particular children and the elderly*”¹³⁰. Recital 8 of the preamble provides even better light on why such consideration is important, stating that “*the safety of products should be assessed taking into account all the relevant aspects, in particular the categories of consumers which can be particularly vulnerable to the risks posed by the products under consideration, in particular children and the elderly.*”

Similarly, to consumer protection we can observe the aim to maintain the high level of protection for safety and health of persons.¹³¹ In this case, the usage of term “persons” might be of importance (even though elsewhere in the directive, it is always consumer to whom high level of protection is linked to). As elaborated before, strict understanding of the term “consumer” does not directly cover infants, however the GSPD does not consider consumer’s health and safety to be the decisive criterion of acceptability. It enlarges its scope to *persons* in general, which allows us to subsume an infant too. Even though the test of foreseeability links the product’s safety to consumer’s expectations, the caregiver’s expectations provide indirectly the protection to the infant. Thus, a trader should anticipate, that even though the product will be primarily handled by the caregiver, it will most probably, where appropriate, come to hands of the infant, who might do a lot of tricks and exercises with it, from eating, through throwing, even to tangling. That makes some products unsafe very easily – ceramic infant plates that might break, long strings that might cause suffocation or way too small objects that might be easily removed from primary objects (not firmly attached beads on clothes or decorations on spoons, etc.). Same principle applies to usage of substances in manufacturing process – even though the caregiver would not taste the product, infant often explores the world

¹²⁹ NAVRÁTIL, Petr; ŠMEJKAL, Václav. *Every consumer or eu citizen only: who benefits from consumer protection law?* In: AUC Iuridica. Charles University. 2013, vol. 59, no. 2, p. 67.

¹³⁰ Article 2, letter (b), subsection (iv) of GPSD

¹³¹ Article 2, letter (b) of GPSD

though touch, especially by mouth¹³², which may disqualify certain substances normally admissible, typically some paints.

Not only does GPSD cover fully some childcare products, it also complements special legislation (cosmetics, electronic goods...), amongst which also legislation protecting primarily children has been adopted¹³³: Food Imitating Products Directive and Toy Safety Directive. The former applies according to Article 1 to products, which, “*appearing to be other than they are, endanger the health or safety of consumers*.” The definition of the “product” then requires likeliness of confusion by consumer, especially children, who in consequence place the product in their mouths, or suck or ingest it, which might be dangerous and cause, for example suffocation or other demonstratively enumerated health risks. The usage of the term consumer is unfortunate and unconceptual, as it disqualifies the youngest of the children. We might attribute this inconsistency mainly to the fact, that the regulation has been adopted 20 years before GPSD. In the light of GPSD, the term “persons” would be more convenient. However, banning the marketing of such imitating products, should be evident, not only by means of systematic interpretation, but also by application of general rules of GPSD, taking into consideration, that once such products are not safe for children who qualify as consumers, how much more unsafe these products are to the youngest children (infants, not qualifying as consumers, if using consumer law definition), whose recognising capabilities are even weaker than those of their older peers.

Toy Safety Directive sets out general and particular requirements that products designed or intended, whether or not exclusively, for use in play by children under 14

¹³² ROCHAT, Philippe. *Object manipulation and exploration in 2- to 5-month-old infants*. Online. Developmental Psychology. 1989, vol. 25, issue 6, p. 871–884. Available at: <https://doi.org/10.1037/0012-1649.25.6.871>. [accessed on 2024-04-29].

¹³³ It must not be omitted that some of other special legislation also focuses on children in some aspects, for example child related car safety requirements set out in Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users.

years of age (“toys”) must meet when placed on EU market¹³⁴. Special needs of infants are recognised in Article 10 covering Essential safety requirements, stating that *“the ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.”* Annexes of the Directive state several particular measures targeting toys intended for children under 36 months (ban of detachable parts that might be swallowed or inhaled, necessity of the toy to be washable, bans and limits of some substances, special warnings), while Commission is entitled to adopt further limits of some chemicals¹³⁵.

From 13th December 2024, GPSD and Food Imitating Products Directive will be replaced by new General Product Safety Regulation¹³⁶. Contrary to GPSD, the criterion for risk acceptability is not anymore high level of protection of health and safety of persons, but those of consumers.¹³⁷ High level of consumer protection is also explicitly mentioned in objective of the regulation.¹³⁸ However, the regulation provides its own definition of consumer as *any natural person who acts for purposes which are outside that person’s trade, business, craft or profession*. Compared to UCPD’s definition, the only difference is, that acting of GPSR consumer is not limited to commercial practices. That might enlarge the understanding of the term “acting”. As the acting is not limited to commercial practices, it is possible to interpret the term extensively as it does not have to be legally binding, which would open the scope to infants’ behaviour too. Although, systematic approach would rather suggest understanding the term analogically to

¹³⁴ Article 2 of Toy Safety Directive

¹³⁵ Article 46 of Toy Safety Directive

¹³⁶ Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC, OJ L 135/1, 23.5.2023. (hereafter referred to as “**GPSR**”)

¹³⁷ Article 2, section 2 of GPSR

¹³⁸ Article 1 of GPSR

consumer law definition¹³⁹. If we apply the historical perspective (of how the scope was defined in GPSD) and the guiding power of the Charter (mainly article 24 on Rights of the child), still, more logical seems to evaluate the safety of the products including infant's perspective. Though necessity of such interpretation renders the omission of the term "persons" unconceptual¹⁴⁰.

Bright sight in relation to children protection in GPSR is evolution of letter (d) in Article 6¹⁴¹ – one additional factor that should be taken into account when assessing safety of a product on top of *the presentation of the product, the labelling, ... any warnings and instructions for its safe use and disposal, and any other indication or information regarding the product* is also labelling regarding age suitability for children. Age indication is an important element influencing the safety of specific product, especially in youngest ages where almost every month counts. Even though such obligation could have logically been deduced out from previous demonstrative list of important factors, explicit mention stresses its importance more effectively.

¹³⁹ Mention of commercial practices does not really extend the nature of acting, as the overall rationale for consumer protection was summarized by CJEU as being „*based on the idea, that the consumer is in a weak position vis-à-vis the seller or supplier, as regards both his bargaining power and his level of knowledge.*“; see to that effect footnote 64 or compare with LOCK, Tobias. *Article 38 CFR. Consumer protection*. In: The EU treaties and the charter of fundamental rights: a commentary. NY: Oxford University Press, 2019, p. 2199.

¹⁴⁰ One might argue, that in fact it was usage of the term "persons" in GPSD, that was unconceptual, taking into consideration strict usage of the term "consumers" elsewhere in the directive, except Article 8, section (c), empowering authorities to take action if a product can pose risk to certain persons. Questionable is though the usage of the term "consumers" at all in product safety law, as practical application would eliminate professionals (across the market, from white to blue collars) using certain products in their work life, but without their profession being in any way linked to understanding of such products (electronic equipment, coffee machine, sanitising detergents, ergonomic chairs, cars etc.). Without application of GPSD/R on their situation, absence of duty on provider to ensure safety of the products seems illogical and necessity of including specific clauses addressing the issue into the contracts between professionals seems to be an unproportional burden and ignorant of day-to-day business reality. Excluding such purchases from professional's due care and granting him consumer status would be also problematic, as it is very unclear, where the differentiating line would end up (f. e.: Would purchase of cell phone for business purposes be a consumer purchase, but contracting business tariff with tariff provider would already fall under professional due care? Positive answer lacks logic and legitimacy, negative one only creates more questions on where contracting is professional "enough", as renting an office or a car might be linked to some professions in very limited way too, whereas such contracts are commonly expecting professional due care when stipulated between professionals for business purposes.)

¹⁴¹ former Article 2, letter (b), point (iii) of GPSD

When it comes to regulation of nutrition, amongst many specific food law legislative acts expanding the general food regulation¹⁴² in sectors where needed, EU took specific action also when tailoring the legislation to needs of infants and young children by adopting separate legislative acts. Regulation 609/2013 is a cornerstone in setting qualitative standards for infant and follow-on formulas (a), processed cereal-based food and baby food (b), food for special medical purposes (c) and total diet replacements for weight control (d). First category concerns infants only, second partially as the term is defined generally as cereals, pasta and biscuits for infants and young children¹⁴³ and last two categories (mainly the FSMPs) might be designed for infants too. Building up on general food law, it sets out additional food safety restrictions (duty of prepacked sale¹⁴⁴, application of precautionary principle¹⁴⁵, general compositional requirements¹⁴⁶, listing of allowed substances¹⁴⁷) together with basic informational duties and restrictions on formula advertising¹⁴⁸. It empowers Commission to further develop more specific requirements basically in all aforementioned areas (compositional requirements and requirements on the use of pesticides in products intended for the production of such food, pesticide residues, labelling, presentation, advertising, and promotional and commercial practices)¹⁴⁹.

Further, we will no longer discuss legislative requirements setting qualitative levels of baby food, toys composition and safety or other childcare products standards, as these are following clear and often scientific principle for which they have been adopted. True is, these are also protecting consumers and subsequently, if not directly, infants and therefore limiting free trade, but their adoption is clearly scientifically substantiated,

¹⁴² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 031/1, 1.2.2002.

¹⁴³ Article 2, section 2, point (e) of Regulation 609/2013

¹⁴⁴ Article 4, section 2 of Regulation 609/2013

¹⁴⁵ Article 5 of Regulation 609/2013

¹⁴⁶ Articles 6-9 of Regulation 609/2013

¹⁴⁷ Article 15, section 1 together with the Annex of Regulation 609/2013

¹⁴⁸ Article 10 of Regulation 609/2013

¹⁴⁹ Article 11 of Regulation 609/2013

legitimising restrictions by preventing health and safety dangers resulting from uncontrolled exposition to some substances or harmful products. The proportionality in these restrictions lies often in setting limits where possible, instead of disproportional total ban of the compounds. They are achieving clear goal of product safety on European market, rather than fairness in commercial practices. The aim to provide consumers with products of certain qualitative level is legitimised by public health protection, whereas even if the adequate substantiation was not present, legislator's wide discretion together with precautionary principle play as strong legitimising factors¹⁵⁰. Of course, both the process of approval of the allowed substances and their limits, both the exact list of substances and their limits might be subject to a scrutiny, though it falls out of the scope of this thesis, as examination of the process does not concern infants directly, but regulated sectors in general, and evaluation of concrete substances and their limits lies primarily on shoulders of scientific community. Legally, we will further concentrate on one specific infant-related area, where more than composition and safety of the product has been regulated – breast-milk substitutes/milk formulas.

2.1. Context of the current BMS Regulation

Regulation *largo sensu* of one category of infant products has gone further than only to set safety standards. Infant formulas, as possible (and sometimes necessary) source of nutrition for infants, are regulated also in area of commercial practices related to these products. The regulation is filling the gap in general regulatory framework trying to set adequate level of consumer protection. In other words, even though breast-milk substitutes meet all food safety and compositional requirements, and their marketing is neither misleading nor aggressive, it can still do a lot of harm when counting in the

¹⁵⁰ See further the Subchapter 3.1.1.2. Health care

complex topic of breastfeeding and possible caregivers' inability to adequately evaluate approach towards nutrition of infants and young children.

2.1.1. Roots of WHO Code of Marketing of Breast-milk Substitutes

In the second half of 20th century, general concern over the marketing of breast-milk substitutes (hereafter referred to also as “BMS”) has widely risen¹⁵¹. Reasons for such counteraction to practices of BMS producers and distributors (who existed on the market for more than a century before¹⁵²) could have been numerous, amongst which notably:

- the development of these practices and their more aggressive character¹⁵³
- spread of the BMS business into developing (meaning low or middle income) countries¹⁵⁴
- general global breastfeeding rates decline¹⁵⁵ caused by combination of factors (availability of BMS products and their marketing, scientific support of formulas, wrong medical and behavioural recommendations in relation to breastfeeding and overall medicalization of breastfeeding, growing urbanization and related socio-cultural changes, evolving position of women in society)¹⁵⁶

¹⁵¹ BOTH, Denise. *The International Code of Marketing of Breastmilk Substitutes: History, Content, and Significance*. Online. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2018, vol. 61, p. 1009. Available at: <https://doi.org/10.1007/s00103-018-2765-4>. [accessed on 2024-04-29].

¹⁵² VÖGELE, Jörg; MARTIN, Michael; RITTERSHAUS, Luisa. *Artificial Infant Nutrition in the Context of Science and Economy in the Late Nineteenth and Early Twentieth Centuries*. Online. *Food and History*. 2014, vol. 2, p. 119–135. Available at: <https://doi.org/10.1484/J.FOOD.5.108965>. [accessed on 2024-04-29].

¹⁵³ STEVENS, Emily E.; PATRICK, Thelma E.; PICKLER, Rita. *A History of Infant Feeding*. Online. *Journal of Perinatal Education*. 2009, vol. 18, issue. 2, p. 36. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2684040/>. [accessed on 2024-04-29].

¹⁵⁴ *Ibidem*.

¹⁵⁵ FOMON, Samuel J. *Infant Feeding in the 20th Century: Formula and Beikost*. Online. *The Journal of Nutrition*. 2/2001, vol. 131, issue 2, p. 411S. Available at: <https://doi.org/10.1093/jn/131.2.409S>. [accessed on 2024-04-29].

¹⁵⁶ BABIĆ, Anđela R. *The Socio-Cultural Context of Breastfeeding in the Nineteenth and Twentieth Centuries*. Online. *Collegium Antropologicum*. 2020, vol. 44, issue 4, p. 245-253. Available at: <https://doi.org/10.5671/ca.44.4.8>. [accessed on 2024-04-29].

- appearance of “hyper-emphatic” motherhood concept, where breast provides not only nutrition, but also emotional attachment and security.¹⁵⁷

Multiple initiatives and repeated actions of various stakeholders towards national authorities or international community¹⁵⁸ were responding to unrestricted or only inadequately regulated commercial practices of BMS producers and new medical findings about impacts of the products on children’s health and development were popping up¹⁵⁹. Interestingly, one of the first initiatives on UN soil originated in the offices of International Organisation of Consumers Unions (IOCU), whose observer approached UN Codex Alimentarius Commission in 1970 with a warning about influence of infant food advertising in developing countries¹⁶⁰ and subsequently in 1972 IOCU submitted its own draft of a code on advertising of infant foods¹⁶¹. Although this qualitative standards and food safety body did not consider the topic in its scope¹⁶², the issue was subsequently discussed on the ground of World Health Organisation and UNICEF in 1979.

¹⁵⁷ ROWOLD, Katharina. „*If We Are to Believe the Psychologists ...*”: *Medicine, Psychoanalysis and Breastfeeding in Britain, 1900–55*. Online. Medical History. 2018, vol. 63, issue 1. Available at: <https://doi.org/10.1017/mdh.2018.63>. [accessed on 2024-04-29].

¹⁵⁸ Notably:

Exclusion of IF advertising to non-medical personnel in US by 1932;

Dr. Cicely Williams’ “Milk and Murder” speech to the Singapore Rotary Club in 1939;

Dr. Derrick Jelliffe coins the term “commerciogenic malnutrition” to describe the negative impacts of the BMS industry’s marketing practices on infant health in 1968;

UK development journal, *The New Internationalist*, runs a cover story, “The Baby Food Tragedy,” a call to action to halt unethical commercial milk marketing in 1973;

British NGO, *The War on Want*, publishes its “Baby Killer” investigation, drawing widespread attention to BMS companies’ deadly practices in low- and middle-income countries in 1974;

Senator Edward Kennedy reaches out to WHO for a global response, and WHO/UNICEF are urged to begin to take legislative action in 1978.

source: ALIVE&THRIVE. *Protecting breastfeeding throughout history: The evolution of the International Code of Marketing of Breastmilk Substitutes*. International Baby Food Action Network. 2021. Available at: https://www.aliveandthrive.org/sites/default/files/timeline_document_a4_v3_0.pdf. [accessed on 2024-04-29].

¹⁵⁹ STEVENS, E. E.; PATRICK, T. E.; PICKLER, R, *op. cit.*, p. 37-38.

¹⁶⁰ Joint FAO/Codex Alimentarius Commission Eight Session. *Report of the fifth session of the Codex Committee on Foods for Special Dietary Purposes*. 1970. 1971, p. 16.

¹⁶¹ Codex Alimentarius Commission Thirteenth Session. *Report Of The Eleventh Session Of The Codex Committee On Foods For Special Dietary Uses*. 1979, p. 2-3.

¹⁶² RICHTER, Judith C. *International regulation of transnational corporations: The infant food debate*. PhD Thesis. Amsterdam University. 2001, p. 47. Available at: <https://hdl.handle.net/11245/1.193514>. [accessed on 2024-04-29].

After a decade-long intense public discussion, including boycott of one of the biggest manufacturers of baby formula – Nestlé¹⁶³, basic milestone in legal framework was achieved on grounds of World Health Assembly (hereafter referred to as “WHA”) – in May 1981 the International Code for Marketing of Breast-milk Substitutes was almost unanimously adopted by resolution WHA 34.22 (118 countries in favour, 1 against – US, 3 abstentions – Argentina, Japan, Korea)¹⁶⁴. As a recommendation towards further regulation in member states, the Code suggested besides other things:

- ban on advertising and sampling of products in scope of the Code (article 5),
- higher informative level of communication targeting pregnant women and mothers (article 4, 9),
- restrictions on health care facilities and health care workers (article 6, 7),
- conflict of interest of employees of BMS manufacturers (article 8).

Scope of the Code, however, was not clear since its initial adoption. Article 2 (Scope of the Code) stated that the Code applies to:

- breast-milk substitutes, including infant formula and
- other milk products, foods and beverages, including bottle-fed complementary foods when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk.

¹⁶³ *Ibidem*, p. 50.

¹⁶⁴ SOKOL, Ellen J. *The Code handbook: a guide to implementing the International Code of Marketing of Breastmilk Substitutes*. IBFAN, Malaysia. 1997, p. 13. Available at: <https://www.babymilkaction.org/wp-content/uploads/2023/06/The-Code-Handbook-2005-with-appendices.pdf>. [accessed on 2024-04-29].

2.1.2. Definition of breast-milk substitute

Although, Article 3 (Definitions) defines “breast-milk substitute” as “any food being marketed or otherwise represented as a partial or total replacement for breast-milk, whether or not suitable for that purpose”. On the next line “Complementary food” is defined as “any food, whether manufactured or locally prepared, suitable as a complement to breast-milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant.” For full picture, also definition of “infant formula” is of importance: “a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age and adapted to their physiological characteristics.”

Articles 2 and 3 are clearly interconnected. However, some interpretative difficulties might pop up. First, when analysing the second part of the scope (other milk products, foods and beverages, including bottle-fed complementary foods when marketed... as a partial or total replacement of breast-milk), it is not clear right away to which products the condition “when marketed as a replacement of breast-milk” applies, whether only to bottle-fed complementary foods or to all the products mentioned. If the condition applies to all the products mentioned, then taking into consideration the definition of breast-milk substitute in Article 3, where key characteristics of breast-milk substitute are “food” which is “being (marketed as) a replacement of breast-milk”, the second part would also cover “breast-milk substitutes” after these having been mentioned in the first part of the scope *expressis verbis*, making the scope wording unnecessarily long and repetitive. Even if we appreciate the addition of beverages in second part (these are not included in breast-milk substitute definition *stricto sensu*), the problem of repetitiveness persists with word “foods”. Illogically however, if we adapt the wording where “other milk products, foods and beverages” stand alone, it would lead to irrational scope of the Code as it would include all the milk products, foods and beverages in the

world (including regular foods for adults). The only possibility how to overcome this illogicality would be by teleological interpretation, narrowing the group only to the milk products, foods and beverages *largo sensu* intended for infants' usage (helping ourselves with "Complementary food" definition that sticks to the age of infant). In that case, these 2 parts of the Scope would just distinguish breast-milk substitutes and complementary foods together with specifying that bottle-fed complementary foods when marketed as a replacement of breast-milk still falls under complementary foods. This definition however excludes the bottle-fed complementary foods marketed as a breast-milk replacement from breast-milk substitutes, creating though the contradiction with definition of breast-milk substitute. To sum up, to preserve the logic, we should stick to the first suggested interpretation specifying all the possible faces of breast-milk substitute, amongst which the infant formula was also mentioned *expressis verbis* in the first part of the Scope and where "being marketed as a breast-milk replacement" is key characteristics of a food or a drink falling under the Code's scope. Such interpretation might be well supported by Introductory Statement by the Representative of the Executive Board to the Thirty-fourth World Health Assembly, delivered before Committee A on 20 May 1981 by dr. Tolbjørn Mork, which was partially attached to Code's publication as Annex 3, even though it was not binding part of the adopted text:

„Products other than bona fide breastmilk substitutes, including infant formula, are covered by the code only when they are “marketed or otherwise represented to be suitable ... for use as a partial or total replacement of breastmilk”. Thus, the code's references to products used as partial or total replacements for breastmilk are not intended to apply to complementary foods unless these foods are actually marketed – as breastmilk substitutes, including infant formula, are marketed – as being suitable for the partial or total replacement of breastmilk. So long as the manufacturers and distributors of the products do not promote them as being suitable for use as partial or total

replacements for breastmilk, the code's provisions concerning limitations on advertising and other promotional activities do not apply to these products."¹⁶⁵

Contrary to dr. Mork as a representative of the Executive Board, some delegations expressed their uncertainty about application of the scope (delegation of Algeria, delegation of Switzerland)¹⁶⁶. However, general expectation of the Code to be revised by the World Health Assembly in near future, if a need for changes was spotted, was in the air¹⁶⁷, as proposed and subsequently adopted resolution stipulated such approach¹⁶⁸. Necessity to adjust the recommendations of the Code to national legal and social conditions has also been reminded by delegation of Switzerland, Brazil and Canada, while Switzerland was also emphasising, that such provision should not play the role of an escape clause.¹⁶⁹

More than 30 years since the adoption of the Code, different official follow-up interpretations came to life. In May 2016, WHO Secretariat issued a report "*Guidance on ending the inappropriate promotion of foods for infants and young children*" where a breast-milk substitute was defined as "*any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks).*"¹⁷⁰ Secretariat also states: "*It should be clear that the implementation of the International Code of Marketing of Breast-milk substitutes and subsequent relevant Health Assembly resolutions covers all these*

¹⁶⁵ Annex 3 to the Code: *Excerpts from the Introductory Statement by the Representative of the Executive Board to the Thirty-fourth World Health Assembly on the Subject of the Draft International Code of Marketing of Breastmilk Substitutes*

¹⁶⁶ WHA. *WHA34/1981/REC/3 – Summary records of Committees*. Thirty-fourth World Health Assembly. 1981, p. 187-197.

¹⁶⁷ *Ibidem*, notably mentioned in speeches of delegation of Algeria, delegation of Netherlands speaking on behalf of whole European Economic Community, delegation of Switzerland, delegation of Turkey, delegation of Canada, but also in the introductory statement of dr. Mork

¹⁶⁸ Resolution *WHA34.22*, article 3.

¹⁶⁹ WHA. *WHA34/1981/REC/3 – Summary records of Committees*. Thirty-fourth World Health Assembly. 1981, p. 187-197.

¹⁷⁰ WHO. *Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual*. World Health Organization, 2017, p. 16. Available at: <https://www.who.int/publications/i/item/9789241513470> . [accessed on 2024-05-05].

products.”¹⁷¹ WHA subsequently appreciated this guidance in its resolution WHA 69.9. The re-definition, however, considers the breast-milk substitutes differently from the one in 1981 WHO Code: it sticks only to milks (or milk alternatives) and strictly sets the age indication – until 3 years of age. Even though the approach of WHO is currently different from what it was 40 years ago, the clutch fact remains, that the Code was adopted in form of a recommendation, that must be incorporated into national legislations by member states’ voluntary initiative in order to become legally binding¹⁷².

2.1.3. Preceding EU BMS legislation

Efforts to regulate the category of breast-milk substitutes can be tracked back to Council Directive 77/94/EEC¹⁷³ and subsequently to the Council Directive 89/398/EEC¹⁷⁴, both regulating foodstuffs for specific nutritional purposes. However, those only laid grounds for adoption of directives imposing specific rules on the category of BMS itself¹⁷⁵. Though, there was never such delegated directive adopted in relation to the former. The directive therefore only provided general rules for all foodstuffs for particular nutritional use (amongst which those for healthy infants were explicitly mentioned¹⁷⁶), such as appropriate composition¹⁷⁷, higher labelling standards¹⁷⁸ and, when it comes to advertising, prohibition on linking the products with human disease cure, treatment or prevention¹⁷⁹. On the contrary, the later reorganised a bit the former, introduced some new general requirements¹⁸⁰ and put much more emphasis on adoption

¹⁷¹ *Ibidem*, p. 8.

¹⁷² SOKOL, E. J., *op. cit.*, p. 11-12.

¹⁷³ Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses, OJ L 026/55, 31.1.1977.

¹⁷⁴ Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, OJ L 186/27, 30.6.1989.

¹⁷⁵ Article 1, section 3 of Directive 77/94/EEC and Directive 89/398/EEC

¹⁷⁶ *Ibidem*, Article 1, section 2, letter (B), point (III)

¹⁷⁷ *Ibidem*, Article 2

¹⁷⁸ *Ibidem*, Articles 4 and 5

¹⁷⁹ *Ibidem*, Article 4

¹⁸⁰ In relation to products fulfilling nutritional needs of infants or young children in good health, the Directive 89/398/EEC provided in Article 7 (2), that instead of indication of nutritional characteristics

of specific directives for each of the specialised foodstuff categories¹⁸¹. In this case, Commission Directive 91/321/EEC¹⁸² was successfully adopted. The delegated directive already referred to the WHO Code, firstly in preamble by invoking conformity to its principles and aims, but with regards to specific conditions in the Community¹⁸³; secondly in Article 1 by stating, that it should enable member states to apply WHO Code principles and aims dealing with marketing, information and responsibility of health authorities.

The delegated directive went to further details when it comes to compositional requirements¹⁸⁴ and elaborated on labelling rules, notably by establishing proper name of the formula products (infant formula, follow-on formula), by prohibiting breast-feeding discouragement¹⁸⁵ and by requiring warnings, preparation instructions, claims restrictions and in case of infant formula (intended for infants up to 4-6 months), also important notice about breast-feeding superiority and necessity to consult the usage of the product with a healthcare professional together with prohibition of idealization and infant images usage¹⁸⁶. Labelling standards were in addition required not only for packaging, but also in advertising.

Infant formula advertising was further restricted in Article 8 cumulatively to scientific and childcare publications and factual information. Superiority of breast-feeding shall not have been undermined. Retail advertising of IF to consumers that might

that was obligatory in labelling, advertising and presentation of other products falling under the scope of the Directive according to Article 7 (1), it was the purpose for which these infant and young children foodstuffs were intended, which had to be indicated.

¹⁸¹ Article 4 of Directive 89/398/EEC

¹⁸² Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae, OJ L 175/35, 4.7.1991.

¹⁸³ „...the rules of composition, labelling and advertising laid down in this Directive should be in conformity with the principles and the aims of the International Code of Marketing of Breast-milk substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the Community.“

¹⁸⁴ Annexes 1 and 2 of Directive 91/321/EEC

¹⁸⁵ Article 7, section 3 in addition provides, that “*The use of the terms 'humanized', 'maternalized', or similar terms shall be prohibited.*” The provision seems to tackle the issue of identifying the formulas with breast-milk, however the width of „similar terms“ is not clear. Addition of term „adapted“ in following acts does bring much more additional clarity.

¹⁸⁶ Article 7 of Directive 91/321/EEC

have induce selling was prohibited (samples, discounts, coupons, special displays...). *“Manufacturers and distributors of infant formulae . [were prohibited]. to provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.”*

Member States were entitled to further restrict the advertising in scientific and childcare publications. They were in the same time required to ensure, that the information spread about infant and young child feeding were objective, consistent and accompanied by several breast-feeding related disclaimers. Additional disclaimers were required in connection to the topic of infant formula. If the information was spread by infant formula manufacturer or distributor, it must have been done on request, through health care system and without mention of IF brand. Donations or low-cost supplies of the IF to institutions shall be addressed strictly for non-breasted babies.¹⁸⁷

Two additional legislative acts tackling the BMS issue were adopted in relation to third countries. Council Resolution 92/C 172/01¹⁸⁸ expressed willingness of the Community to assist as a mediator in dealing with BMS marketing issues in third countries when such an activity would be carried out by Community-based manufacturers. Council Directive 92/52/EEC¹⁸⁹ then also imposed some of the compositional and labelling Community rules adopted in Directive 91/321/EEC to IF and FOF exported to third countries.

Most of the limitations remained the same in Commission's Directive 2006/141/EC¹⁹⁰, which recast the directive 91/321/EEC. Though some changes were introduced. Definition of infant and follow on formulas were clarified based on

¹⁸⁷ *Ibidem*, Article 9

¹⁸⁸ Council Resolution of 18 June 1992 on the marketing of breastmilk substitutes in third countries by Community-based manufacturers, OJ C 172/01, 8.7.1992.

¹⁸⁹ Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries, OJ C 179/129, 1.7.1992.

¹⁹⁰ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401/1, 30.12.2006.

recommendations of the Codex Alimentarius Committee.¹⁹¹ The compositional safety and suitability was even more highlighted, now it required regular review and the topic of pesticides was elaborated.¹⁹² Notification process has been kicked-off.¹⁹³ Labelling provisions did not bring much new, only a clear distinction between IF and FOF has become required. The same conclusion can be reached in connection to provisions dealing with marketing. When looking into the wording of the references to the Code in the Preamble (Recital 27) and in Article no. 1, the diction remained without change. The Directive 89/398/EEC was also recast by the Directive 2009/39/EC¹⁹⁴. New elements in this Directive were though mainly of procedural character, putting more emphasis on the involvement of the Commission.

2.2. Current EU BMS legislation

Both recasts (2006/141/EC and 2009/39/EC) were repealed by Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. As mentioned above,¹⁹⁵ the regulation sets out general rules applicable also to the category of infant and follow-on formulas. It very well follows the previous legislation by combining the clauses of previous acts. Except the definitions of the terms which remain identical with previous Directive 2006/141, it also preserves the prohibition of curing properties indication, without prejudice to spread of the information to healthcare professionals. Breastfeeding discouragement, that might be caused by labelling, presentation and advertising of IF or FOF has been also prohibited. The ban on infants depiction has been extended from IF labelling to all the labelling, presentation and advertising of infant formula, and also the

¹⁹¹ Article 2 of Directive 2006/141/EEC

¹⁹² *Ibidem*, Articles 5 and 6, Article 10

¹⁹³ *Ibidem*, Article 9

¹⁹⁴ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ L 124/21, 20.5.2009.

¹⁹⁵ Chapter 2. Regulatory protection of infants, p. 27

labelling of follow-on formula. Interestingly, it has resurrected the precautionary principle clause.¹⁹⁶ Other clauses from Directive 2006/141 were not embodied directly in the regulation, but were left to Commission's delegated acts.

The regulation empowers Commission in Article 11 to adopt delegated acts with respect to, besides compositional, informational and notification requirements, “*the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims in relation thereto*” and “*the requirements concerning promotional and commercial practices relating to infant formula.*”¹⁹⁷ Commission indeed adopted several delegated acts, amongst which the Commission Delegated Regulation No 2016/127 as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (hereafter referred to as “Delegated Regulation 2016/127” or “BMS Regulation”). Even though the Regulation 609/2013 does not refer to the WHO Code anymore, the delegated one preserves the reference in its preamble and follows the diction of previous legislative acts with several expansions¹⁹⁸.

In the context of evolution of the WHO Code BMS definition understanding, it is worth noting, that in the Recital 31 of the preamble of the Regulation 609/2013 (which defined infant as a child under the age of 12 months), there is a note about increasing number of milk-based drinks and similar products on the Union market which are promoted as being particularly suitable for young children (defined as children between

¹⁹⁶ Article 5 of Regulation 609/2013

¹⁹⁷ Article 11, section 1, letter (c) and (e).

¹⁹⁸ Recital 21: “*...In this context, the EU Action Plan recognised the continuous importance of the World Health Organisation (WHO) International Code of Marketing of Breast-milk substitutes, on which Directive 2006/141/EC was based. The WHO Code, adopted by the 34th World Health Assembly, aims at contributing to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes. It includes a series of principles related to, among others, marketing, information and responsibilities of health authorities.*”

Recital 24: *It is therefore necessary to lay down requirements in order that such information ensures an adequate use of the products in question and is not counter to the promotion of breast feeding, in line with the principles of the WHO code.*

1 and 3 years of age). The recital furthermore states, that these products “*are not covered by the existing specific measures applying to food intended for infants and young children. Different views exist as to whether such products satisfy the specific nutritional requirements of the population group they target.*” The Commission is also asked to consult the topic with European Food Safety Authority (hereafter referred to as “EFSA”) and potentially present a legislative proposal¹⁹⁹. However, such proposal did not come out as the discussion²⁰⁰ have not so far reached a positive opinion when it comes to necessity of another legislation. Another point worth noting in relation to the preamble is the usage of the term “consumer”²⁰¹ which implicitly attributes such status also to the infants. Such terminology seems, when compared to Consumer law, inappropriate. Though, the problem is not present only in the latest regulation but can be tracked back in smaller extent also to the previous legislative acts.²⁰² On the other hand, in some cases, the used term is also “humans”²⁰³ or “population”²⁰⁴, which is more compliant with consumer law, though mixing the terms hardens understanding of the terminology.

When it comes to delegated acts, notably Delegated Regulation 2016/127 once again builds on its predecessor. It provides new version of compositional requirements, brings changes to nutritional information and develops notification duties, but except of that, it does not substantially derive from previous text when it comes to labelling and advertising restrictions. For example, in Article 6, section (6), it only additionally describes how the IF and FOF distinction should look like, as it should “*enable consumers to make a clear distinction between them, in particular as to the text, images and colours used*”. Nevertheless, also few important changes were introduced. Nutritional and health

¹⁹⁹ The obligation was also embodied in Article 12 of Regulation 609/2013.

²⁰⁰ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). *Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union*. Online. EFSA Journal. 2013, vol. 11, issue 10. Available at: <https://doi.org/10.2903/j.efsa.2013.3408>. [accessed on 2024-04-30].

²⁰¹ The term might be understood in ambiguous way notably in Recital 26, but also in Recital 39 and Article 15, section (6) and Article 16, section (1) of Regulation 609/2013.

²⁰² Recital 8 and 10 of Directive 2009/39

²⁰³ Recital 14 of Directive 2009/39

²⁰⁴ Recitals 3, 10, 15, 21 of Regulation 609/2013

claims were completely forbidden in connection to infant formula²⁰⁵ and some advertising clauses and information duties in articles 10 and 11 obtained direct effect, while Member states action was needed under the Commission Directive 2006/141/EC. Finally, the delegated regulation *expressis verbis* characterises infants as vulnerable consumers in Recital 5, following in Regulation's 609/2013 footsteps.

Delegated Regulation 2016/128 then tackles the topic of infant food for special medical purposes, replacing previous legislation²⁰⁶, that did not take account of specificities of infant food sector and allowed infant FSMP to be marketed without same restrictions as IF products²⁰⁷. Except of its own compositional requirements, it is in relation to informational requirements and advertising generally stricter than BMS regulation. It applies similar restrictions to those adopted in relation to IF, but the scope of the regulation is not limited to products intended for infants up to 6 months of age, but for all the FSMPs developed to satisfy the nutritional requirements of infants.²⁰⁸

²⁰⁵ Article 8 of Delegated Regulation 2016/127

²⁰⁶ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, OJ L 091/29, 7.4.1999.

²⁰⁷ Recital 18 of Delegated Regulation 2016/128

²⁰⁸ *Ibidem*, Article 8

3. Conformity of the BMS regulation with European Union Charter of Fundamental Rights

3.1. List of stakeholders and their affected rights

Multiple stakeholders are influenced by current EU regulatory framework protecting infants in the area of breast-milk substitutes. Except of the infants, whose interests are cornerstone of the regulation, we can see also other subjects highly impacted. Clearly, manufacturers and distributors of BMS products are limited in scope of their marketing practices. However, consideration of caregivers group is of significant importance too. Their interests, on one hand protected, but on the other limited, have not yet been seriously taken into consideration. Following analysis would like to deal not only with the clash that appears at the first sight – the one between interests of the child and those of manufacturers and distributors, but also to include caregivers' interests, as long as guaranteed by EU Charter of Fundamental rights. After careful identification of fundamental rights in stake, we shall proceed with balancing of the interests, applying practices adopted by the Court of Justice of the European Union. We shall consider different regulatory modulations in our search for more just and substantiated arrangement, if necessary.

3.1.1. Infants

3.1.1.1. Rights of the child

“The combination of Article 3 of TEU, Article 24 of the Charter and the Commission Communication of 2006 provides an excellent basis to develop policies at EU level which effectively take the best interests of the child into account.”²⁰⁹

²⁰⁹ GARDE, A., *op. cit.*, p. 175.

Article 24 of the Charter states besides others:

“Children shall have the right to such protection and care as is necessary for their well-being. “...

„In all actions relating to children, whether taken by public authorities or private institutions, the child’s best interests must be a primary consideration.“

Article 24 builds upon Article 3 of Children’s Rights Convention.²¹⁰ Both “right to well-being” and “primary consideration (of child’s best interest)” are though at first sight indeterminate.²¹¹ As other social rights, right to necessary care and protection for child’s well-being is preconditioned by current social advancement and laws of each specific country.²¹² We might see the significance of the clause in giving children the passive voice by classifying them as subject worth noticing and *requiring additional protection*²¹³, contrary to policy oriented social human rights shading light on different key valuable objectified values (f.e. Article 35 – Health care, Article 37 – Environmental protection etc.). Similar approach might be observed in Articles 25 (Rights of the elderly) or Article 26 (Integration of persons with disabilities). The duty to create such protective and careful environment has been put on shoulders of EU and Member states when adopting EU law.²¹⁴ The best interest rule is also very hard to grasp, as in its nature, it is

²¹⁰ LAMONT, R., *op. cit.*, p. 707-711.

²¹¹ LANG, Iris G. *The child’s best interests as a gap filler and expander of EU law in internal situations*. Online. In: Research handbook on general principles in EU law: constructing legal orders in Europe. Edward Elgar Publishing, 2022, p. 563. Available at: <https://doi-org.ezproxy.is.cuni.cz/10.4337/9781784712389.00019>. [accessed on 2024-05-04].

²¹² Typically, right to health care, depending on situation in each Member state, is even preconditioned to national laws and practices explicitly by the Charter in Article 35

²¹³ LOCK, Tobias. *Article 24 CFR. The rights of the child*. In: The EU treaties and the charter of fundamental rights: a commentary. NY: Oxford University Press, 2019, p. 2174.

²¹⁴ *Ibidem*.

flexible in application.²¹⁵ It surely has power to guide the interpretative work,²¹⁶ but does it embody more?²¹⁷

The uncertainty floats under the surface of otherwise brilliant Garde's analysis of inadequate (primary) consideration of child's best interest.²¹⁸ Space for even higher protection does not persuasively seem as a proof of unconsidering approach of the regulator. However, what then constitutes an adequate consideration when we objectively know, that especially in the domain of human rights, there is always room for higher protection and the balancing is the daily bread of the judge?²¹⁹ Deducing from the word "primary", instead of f.e. "paramount", it should be considered as one of important factors, rather than the most important factor.²²⁰

Taking off from the word "necessary", it is clear, that the protection (and care) should be of such nature, that without them the child would fall victim to imminent, clear or grave suffering. Less clear are the other forms of suffering: subtle, uncertain or not yet widely explored ones. Are these also covered by Article 24? Nature of social rights does not provide exact answer,²²¹ neither adequately does the CJEU case-law.²²² In family and free movement of persons cases, CJEU has already quite developed set of criterion for determining the best interest of concrete child (stability, relationship with a parent...).²²³ However, a standardised approach has not yet been adopted, leaving the room only for

²¹⁵ *Ibidem*.

²¹⁶ Case C-335/17, *Valcheva*, ECLI:EU:C:2018:359, para. 36.

²¹⁷ LAMONT, R., *op. cit.*, p. 712.

²¹⁸ GARDE, A., *op. cit.*, p. 184 – 194.

²¹⁹ In relation to child's best interest, see case C-483/20, *Commissaire général aux réfugiés and aux apatrides (Unité familiale - Protection déjà accordée)*, ECLI:EU:C:2022:103, demonstrating that the principle is not almighty.

²²⁰ LAMONT, R., *op. cit.*, p. 720.

²²¹ f.e. according to Case C-709/20, *The Department for Communities in Northern Ireland*, ECLI:EU:C:2021:602, the consideration of a Member State whether to provide social assistance to a citizen and children for whom he is responsible, should take into account actual and current risk of violation of fundamental rights. In relation to these fundamental rights, the court invoked right to Human dignity (Article 1) and Respect for private and family life (Article 7) in conjunction with child's best interest (Article 24(2)).

²²² LAMONT, R., *op. cit.*, p. 712.

²²³ LONARDO, Luigi. *The best interests of the child in the case law of the Court of Justice of the European Union*. Online. Maastricht Journal of European and Comparative Law. 2022, vol. 29, issue 5, p. 599. Available at: <https://doi.org/10.1177/1023263X221144829>. [accessed on 2024-04-30].

individual consideration.²²⁴ What can then be applied in the domain of free movement of goods, especially within policy evaluation process, where only children in general²²⁵ are concerned?

In *Dynamic Medien* case²²⁶, Germany adopted restrictions on mail orders of image storage media in order to protect children. The court upheld such limitation of free trade after running the proportionality test.²²⁷ It ruled the protection of the child to be a legitimate interest justifying the restriction on a fundamental freedom, such as the free movement of goods. At the same time, it supported its suitability to attain the goal and also considered the restriction not to go beyond what was necessary, as the trade of concerned goods was not excluded absolutely, but was limited to in person purchases where the certainty, that unauthorised materials would not be sold to minors, could be achieved. Even though the court applied the test of proportionality in relation to the rights of the child, it did not bring additional light on what these rights mean²²⁸.

Except of that, we might only implicitly deduce from the case law on child's best interest more general abstraction on how the best interest should be assessed. What the court in each of the cases does is the deep analysis of the specific situation, extraction of set of important criterions in the child's interest and subsequent evaluation on how these could be met in best possible way (among the options in stake). In *Chavez-Vilchez*, list of criteria comprises age of the child, the child's physical and emotional development, extent of emotional ties to parent and third country national, risks of separations on child's equilibrium.²²⁹ In *SM*, it was the age of the child, length of his relationship with his guardians, the closeness of the such personal relationship and the extent of child's

²²⁴ *Ibidem*, p. 602-603.

²²⁵ Best interest of children as a general group has been of importance in ECHR mandatory vaccination case *Vavříčka and Others v. the Czech Republic* of 8.4.2021 . [GC]. - 47621/13, 3867/14, 73094/14 et al.

²²⁶ Case C-244/06, *Dynamic Medien*, ECLI:EU:C:2008:85

²²⁷ *Ibidem*, para. 42-48.

²²⁸ *Ibidem*, para. 41.

²²⁹ Case C-133/15, *Chavez-Vilchez and others*, ECLI:EU:C:2017:354, para. 71.

dependency.²³⁰ Another complex consideration was adopted in relation to family reunification in *K and B*, where the attention was paid to minor age of children, family relationships solidity, the duration of residence and of the existence of family, cultural and social ties with country of origin.²³¹ In some cases, even mere classification of children as “particularly vulnerable” entitled them for additional protection.²³² Even though such conclusion does not zoom in the best interest substantively, it instructs us on how the consideration should occur – it should complexly take into account all the relevant circumstances.

3.1.1.2. Health care

“It is axiomatic, that children also benefit from the protection of other Charter rights.”²³³ Article 35 provides for, *inter alia*, high level of human health protection within implementation of EU policies, while precautionary principle has been deduced as part of such approach. CJEU referred to the principle while acknowledging restriction on other fundamental rights in *Neptune Distribution*.²³⁴ The court balanced the restriction on freedom of expression and freedom to conduct the business (both in area of commercial communication) with protection of consumers health.²³⁵ It acknowledged wide discretion of legislator to choose appropriate restriction in achieving its goals²³⁶, while uncertainty about “*the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures.*”²³⁷ Both existence and extent of

²³⁰ Case C-129/18, *SM (Child placed under Algerian kafala)*, ECLI:EU:C:2019:248, para. 69.

²³¹ Case C-380/17, *K and B*, ECLI:EU:C:2018:877, para. 52.

²³² Cases C-648/11, *MA and others*, ECLI:EU:C:2013:367, para. 55; and C-147/17, *Sindicatul Familia Constanța and Others*, ECLI:EU:C:2018:926, para. 71.

²³³ LOCK, T., *op. cit.*, p. 2174.

²³⁴ Case C-157/14, *Neptune Distribution*, ECLI:EU:C:2015:823.

²³⁵ *Ibidem*, para 75.

²³⁶ *Ibidem*, para 76.

²³⁷ *Ibidem*, para. 82, referring to case C-269/13, *Acino v Commission*, ECLI:EU:C:2014:255, para. 58.

the risk are therefore not of essential importance in acknowledging the legitimacy of a restriction striving to protect public health, provided that the scientific knowledge does not already assessed the risk adequately to balance the interest in more proportional way.

In second tobacco advertising case *Germany v Parliament and Council*²³⁸, CJEU was standing also before the task to balance freedom of expression with protection of public interest (notably protection of health). EU ban on general advertising of tobacco and tobacco products in printed and digital media was considered appropriate to attain the goal of high level of human health protection. Proportionality was seen in not banning the advertising absolutely, as the possibility to advertise in publications intended for professionals in the tobacco trade or published in third countries and not intended primarily for the Community market, was preserved. At the same time, less restrictive measure (excluding some form of media) would render the restriction unsure and uncertain which would prevent the regulation to achieve its harmonizing objective.²³⁹

Another tobacco case landed before the CJEU in 2014 – in *Philip Morris*²⁴⁰, the regulatory requirements on labelling were questioned, *inter alia*. Same as in *Deutsches Weintor*²⁴¹ and *Neptune Distribution*, the court firstly ruled out, that the essence of freedom of speech was not affected by the restrictions as those were targeting specific area and only certain kind of information.²⁴² In paragraph 153, CJEU states that in relation to the proportionality principle, it must be noted “*that the second sentence of Article 35 of the Charter and Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU require that a high level of human health protection be ensured in the definition and implementation of all the Union’s policies and activities.*” Without further direct explanation what high level of health protection means, the court came back to some sort of scaling in paragraph 156, stating: “*human health protection — in an area characterised by the proven harmfulness*

²³⁸ Case C-380/03, *Germany v Parliament and Council*, ECLI:EU:C:2006:772.

²³⁹ *Ibidem*, para. 144-158.

²⁴⁰ Case C-547/14, *Philip Morris*.

²⁴¹ Case C-544/10, *Deutsches Weintor*, ECLI:EU:C:2012:526.

²⁴² Case C-547/14, *Philip Morris*, para. 151.

of tobacco consumption, by the addictive effects of tobacco and by the incidence of serious diseases caused by the compounds those products contain that are pharmacologically active, toxic, mutagenic and carcinogenic — outweighs the interests put forward by the claimants in the main proceedings.” Afterwards the second sentence of Article 35 is repeated, underlining court’s intention to shed light on its meaning. In light of seriousness of the danger to human health and EU law requirement of high level of health protection, a measure thriving for such protection is proportionally restricting freedom of speech²⁴³, provided it does not go beyond what is necessary. Such necessity is demonstrated on multiple levels:

1. CJEU finds warnings ineffective without additional prohibition of sort of “positive impression” that the labelling may invoke and even considers such labelling counterproductive to understanding of seriousness of the warnings.
2. CJEU dismissed a possibility, that less strict additional regulation or surplus warning duties instead of prohibition of some labelling features would be sufficient, as such features might have opposite, rather motivational effect.
3. CJEU considered such warnings rather to exploit vulnerability of consumers of tobacco products, who are, because of their nicotine dependency, particularly receptive to messages that might in any way suggest benefit or reduced risk.²⁴⁴

First and second reasons, as to the effectiveness and counterproductive effect, can be understood in the light of court’s approach towards assessing highly complex scientific and technical facts. In *Swedish Match*²⁴⁵, it stated that “*in order to determine whether the prohibition on the placing on the market of tobacco products for oral use is proportionate,*

²⁴³ In situation, where the freedom of speech has also economic connotations (see *Neptune Distribution*, para 64.), it is important to mention CJEU’s standpoint, that “*in accordance with settled case-law, the objective of the protection of health takes precedence over economic considerations, the importance of that objective being such as to justify even substantial negative economic consequences* (case C-151/17, *Swedish Match*, ECLI:EU:C:2018:938, para. 54 and cited case-law; subsequently reaffirmed also in caase C-452/20, *Agenzia delle dogane e dei monopoli and Ministero dell'Economia e delle Finanze*, ECLI:EU:C:2022:111, para. 50)

²⁴⁴ Case C-547/14, *Philip Morris*, para. 159-160.

²⁴⁵ Case C-151/17, *Swedish Match*, ECLI:EU:C:2018:938.

it must be recalled that the Courts of the European Union cannot substitute their assessment of that material for that of the legislature on which the FEU Treaty has placed that task. The EU legislature's broad discretion, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts.²⁴⁶ Indeed, the court referred to substantiation in Recitals 25 and 27 of the contested directive²⁴⁷ in paragraphs 140 and 142.

Last part of CJEU's reasoning considers tobacco consumers vulnerable, which must be read together with paragraph 144, where this class of consumers is explicitly described as particularly vulnerable. In the same paragraph, the court states that prohibition of even factually accurate information, that might however encourage consumption of tobacco products, because of possible consumers interpretation as to the product related benefits or risk-reduction, falls under the scope of "high level of protection of human health". Again, the application of precautionary principle is visible in court's assessment.

Another fragmented approach was presented in *Deutsches Weintor* case, where the nature of the product – wine, played role when considering conformity of a health claim accompanying such product. Provision of claim "easily digestible", without addressing negative part of alcohol consumption, was considered misleading, even when factually correct due to different composition of concerned wines.²⁴⁸

²⁴⁶ *Ibidem*, para. 37 and preceding cases C-5/16, *Poland v Parliament and Council*, ECLI:EU:C:2018:483, para. 150-151; C-343/09, *Afton Chemical*, ECLI:EU:C:2010:419, para. 28, 33; C-310/04, *Spain v Council*, ECLI:EU:C:2006:521, para. 121.

Contrary to former cases, in *Swedish Match* CJEU did not reaffirmed legislator's duty to "be able to produce and set out clearly and unequivocally the basic facts which had to be taken into account as the basis of the contested measures of the act and on which the exercise of their discretion depended." Instead, it invoked his duty to take account of precautionary principle (as formulated in *Neptune Distribution*) and mentioned health risks examined by the Commission that legitimized the adopted measures.

²⁴⁷ Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127/1, 29.4.2014.

²⁴⁸ Case C-544/10, *Deutsches Weintor*, para. 50-52.

3.1.2. Caregivers

3.1.2.1. Consumer protection

Except of what was described in Chapter 1, high level of consumer protection in combination with Articles 169 and 52 TFEU imposes upon Union the duty to contribute to consumers health, safety and economic interests, as well as to promote their right to information, education and to organize themselves.²⁴⁹ Such contribution might conflict with other rights guaranteed by the Charter, but its importance may justify even substantial negative economic consequences for certain economic operators.²⁵⁰ Less permissive approach of the Court is though hold when tackling national consumer protection rules conflicting free movement law, where very much depends on the “secondary object of protection” – purely economic interests are dismissed more than national rules protecting health.²⁵¹

*“From a constitutional theory perspective, consumer protection provisions should be treated as constitutional principles or programme norms. They are used to protect weaker party to a contract, although only in a limited scope.”*²⁵² Article 38 is even considered to be unlikely to cause by itself any significant alteration to particular disputes.²⁵³ It should be understood rather as a relatively important interpretative principle²⁵⁴ and more importantly, as an element closely linked to harmonizing legislative process, as the Article 38 is reflected in Articles 114 and 169 TFEU – high level of

²⁴⁹ LOCK, T., *op. cit.*, p. 2199.

²⁵⁰ Case C-12/11, *McDonagh*, ECLI:EU:C:2013:43, para. 48.

Still, high level of protection does not legitimise the trader to bear any imaginable burden, see f.e. case C-5/19, *Overgas Mrezhi and Balgarska gazova asotsiatsia*, ECLI:EU:C:2020:343, para. 85-87.

²⁵¹ WEATHERILL, Steve. *Article 38 – Consumer Protection*. In: *The EU Charter of Fundamental Rights: a commentary*. Second edition. Hart Publishing, 2021, p. 1071.

²⁵² JAGIELSKA, Monika; JAGIELSKI, Mariusz. *Are consumer rights human rights?* Online. In: *European Consumer Protection: Theory and Practice*. 2012, p. 346. EBSCO. <https://search.ebscohost.com/login.aspx?direct=true&db=e000xww&AN=443656&lang=cs&site=ehost-live>. [accessed on 2024-04-26].

²⁵³ WEATHERILL, S., 2021, *op. cit.*, p. 1069

²⁵⁴ ŠMEJKAL, V., *op. cit.*, p. 1588.

consumer protection must be therefore pursued while adopting market integrating measures by EU legislator.²⁵⁵ However, it must be borne in mind that high level does not mean the highest²⁵⁶.

3.1.2.2. Freedom of information

Freedom of information is guaranteed as part of freedom of expression in Article 11 of the Charter. Both receiving and imparting of information are protected, after all these are interconnected, as receiving information highly influences their further sharing.²⁵⁷ As mentioned in previous subchapter, receiving information in form of right to information is protected also as part of consumer protection law. Provision of adequate and non-misleading information are among other protective measures, crucial for consumers to make informed and rational choices.²⁵⁸ Of course, application of gathered information can be altered by different variables during decision making process, from how the information is displayed²⁵⁹ to overall context of the purchase²⁶⁰ but without factual substrate, the decision could not be, *per se*, informed and even “average consumer” concept where consumer is reasonably well-informed, observant and circumspect, would not be applicable. The principle applies even to the importance of quantity of information, where more does not have to be better.²⁶¹ Right to be informed

²⁵⁵ WEATHERILL, S., 2021, *op. cit.*, p. 1075.

²⁵⁶ Case C-233/94, *Germany v Parliament and Council*, para. 48.

²⁵⁷ LOCK, Tobias. *Article 11 CFR. Freedom of expression and information*. In: The EU treaties and the charter of fundamental rights: a commentary. NY: Oxford University Press, 2019, p. 2135.

²⁵⁸ WILLMAN-IIVARINEN, Hanna. *The future of consumer decision making*. Online. European Journal of Futures Research. 2017, vol. 5, p. 3. Available at: <https://doi.org/10.1007/s40309-017-0125-5>. [accessed on 2024-05-01].

for practical demonstration, see f.e. YUAN, Rao; JIN, Shaosheng; WU, Wenchao. *Interactive effects of information and trust on consumer choices of organic food: Evidence from China*. Online. Appetite. 2024, vol. 192, no. 107115. Available at: <https://doi.org/10.1016/j.appet.2023.107115>. [accessed on 2024-05-01].

²⁵⁹ BIALKOVA Svetlana; van TRIJP, Hans. *What determines consumer attention to nutrition labels?* Online. Food Quality and Preference. 2010, vol. 21, issue 8, p. 1050. Available at: <https://doi.org/10.1016/j.foodqual.2010.07.001>. [accessed on 2024-05-01].

²⁶⁰ WILLMAN-IIVARINEN, H., *op. cit.*, p. 4-5.

²⁶¹ BENN, Yeal; WEBB, Thomas L.; CHANG, Betty P.I.; REIDY, John. *What information do consumers consider, and how do they look for it, when shopping for groceries online?* Online. Appetite. 2015,

should therefore be read rather as “properly informed” than “informed as much as possible”.

Freedom of information applies not only to the content itself, but also to the means of transmission and reception.²⁶² It may be infringed, not only in direct clash with another right²⁶³, but also complementarily to restriction on freedom to conduct a business, or rather freedom of (commercial) expression. In *UPC Telekabel Wien*²⁶⁴, an internet service provider, who had to chose measures in order to restrict access to content violating intellectual property law, was called obliged to ensure compliance with the right of internet users to freedom of information.²⁶⁵ Such compliance would consist in adopting strictly targeted measure without affecting internet users lawfully accessing information.²⁶⁶ The restriction on freedom of information is therefore legitimate as far as it lawfully pursues the other legitimate objective. Even though the court did not undergo a proportionality test, the condition of “strict targeting” might be considered as a very curtailed modulation in situation, where clear breach of intellectual property was seen in the first place.

3.1.2.3. Right to engage in work, equality between women and men, integrity

Article 15, affirming right to engage in work, is constructed as a freedom right, which also Explanations to the Charter provide for, stating it is based upon Article 1, section 2 of European Social Charter.²⁶⁷ It does not impose a duty upon EU or Member

vol. 89, p. 272. Available at: <https://doi.org/10.1016%2Fj.appet.2015.01.025>. [accessed on 2024-05-01].

²⁶² WOODS, Lorna. *Article 11 – Freedom of Expression and Information*. In: The EU Charter of Fundamental Rights: a commentary. Second edition. Hart Publishing, 2021, p. 349.

²⁶³ Typically in cases where access to information is prohibited by public body, see f.e. case T-590/10, *Thesing and Bloomberg Finance v ECB*, ECLI:EU:T:2012:635, para. 73-81.

²⁶⁴ Case C-314/12, *UPC Telekabel Wien*, ECLI:EU:C:2014:192.

²⁶⁵ *Ibidem*, para. 55.

²⁶⁶ *Ibidem*, para. 56.

²⁶⁷ “With a view to ensuring the effective exercise of the right to work, the Parties undertake:

states to guarantee a job post for everyone. Instead, they are asked not to interfere with one's free choice.²⁶⁸ The Charter protects both dependant work and self-employment²⁶⁹, conceptually it is not impossible, that the freedom under the Charter could convey also non-profit occupation.²⁷⁰ Of course, also the rights under Article 15 might be limited, one is even introduced directly by the Charter in Article 32, prohibiting child labour. Still, limitations must be based on legitimated objective, as all limitations of fundamental rights do.²⁷¹

In relation to caregivers of infants, they are naturally limited in their possibilities due to their caretaking responsibilities.²⁷² In case of breastfeeding women, these are limited in their options when trying to get back to labour market after the childbirth, due to the frequency of the feeding and other necessary care.²⁷³ It must be noted, that difficulties of such nature have declining tendency as the child grows older. Notably after the introduction of complementary foods, the possibilities of the caregiver widen. However, in course of exercising their right to engage in work, being aware of the limitations, it is also natural, that they consider their possibilities, notably by exploring enabling alternatives (caretaking facilities, services, help from relatives, feeding alternatives...). During first 6 months, when infant is in terms of nutrition completely dependent on mother's milk (or its substitute), it is understandable that a breastfeeding

...
 (2) *to protect effectively the right of the worker to earn his living in an occupation freely entered upon;*”
²⁶⁸ FOREJTOVÁ, Monika. *Article 15. Freedom to choose an occupation and right to engage in work*. In: Treaty on the Functioning of the European Union ; Treaty on European Union ; Charter of Fundamental Rights of EU: a commentary. Wolters Kluwer. 2022, p. 1527.

²⁶⁹ LOCK, Tobias. *Article 15. Freedom to choose an occupation and right to engage in work*. In: The EU treaties and the charter of fundamental rights: a commentary. NY: Oxford University Press, 2019, p. 2145.

²⁷⁰ The wording is different from one in ESC, replacing words “earn the living in occupation freely entered upon” by the term “engage in work and to pursue a freely chosen or accepted occupation”. The profitability of the activity under ESC Article 1 (“*earn the living*”) is not that clear from phrasing of Article 15 of the Charter.

²⁷¹ Joined cases C-159/10 and 160/10, *Fuchs and Köhler*, ECLI:EU:C:2011:508, para. 50.

²⁷² SCHIEK, Dagmar; KOTEVSKA, Biljana. *Article 23 – Equality between Women and Men*. In: The EU Charter of Fundamental Rights: a commentary. Second edition. Hart Publishing, 2021, p. 673.

²⁷³ The care, of course, does not have to be provided by women exclusively, it is however hard to imagine practical separation of the duties in such manner, that the woman could jump back into most of work load modulations in between the feedings.

mother, if trying to exercise her right to engage in work already, explores possible surveillance over the child for specific amount of time (depending on the length of the shifts) and also options of fulfilment of its nutritional needs.

During the decision-making process, such woman would therefore become consumer, who at least searches through the market (be it either in connection with BMS products, breast pumps or wet nursing services, where possible). For exercise of the Article 15 right, it is crucial not only that she can, if she decides, purchase a nutritional solution, that would enable her to leave the child for longer period of time, but also that she accesses the adequate information²⁷⁴ she needs to conduct the decision-making process properly, as it influences how she decides to engage in a work. Even though the adequate provision of information, as discussed above, is in fact following mainly the principle of freedom of (receiving) information under Article 11 and is part of the consumer protection under Article 38 in the context of commercial information that serve consumer, it is also an important factor playing role in the decision-making about the engagement in work itself, its extent and the type of the work, especially in situation where the caregiver himself is balancing his right to work with fulfilling his caretaking duties.

In case of comparing the possibilities in exercise of right to work between women and men, breastfeeding is also generally disadvantaging the former if seeking a job, thus creating sort of inequality in the area of employment. Article 23 states, that “*equality between women and men must be ensured in all areas, including employment,*” ... Therefore, even policies pursuing other aim than equality, must also promote it.²⁷⁵ Ensuring the equality, as a positive dimension of non-discrimination, is what primarily distinguish Article 23 from Article 21.²⁷⁶ Such positive dimension consists not only of guaranteeing and strengthening formal equality, but sometimes also of “*granting*

²⁷⁴ Case C-157/14, *Neptune Distribution*, para 74.

²⁷⁵ SCHIEK, D.; KOTEVSKA, B., *op. cit.*, p. 669.

²⁷⁶ *Ibidem*, p. 670.

*additional privileges to those who have hitherto suffered detriment.*²⁷⁷ *Ensuring equality might then require even taking of specific measures in favour of women overcoming factual disadvantage.*²⁷⁸ From the opposite perspective, if a provision contributes to inequality only indirectly, it may still be justified by a legitimate aim, if the means of achieving that aim are appropriate and necessary.²⁷⁹ Protection of public health can be considered as such objective. In *Léger*, CJEU did not rule out French discriminatory practice excluding homosexual men from blood donations permanently, but instructed national court to examine, whether there wasn't less restrictive measure.²⁸⁰

Last but not least, even though breastfeeding creates very strong emotional bond between mother and child, it might (also simultaneously) become intrusive for the mother. In that case, woman might feel under pressure to continue because of emotional and child's health reasons. Her physical integrity, as a freedom from interferences with her body, is then under pressure.²⁸¹ Right to respect for one's physical integrity is enshrined in Article 3 of the Charter. As physical integrity concerns also freedom in area of reproductive health,²⁸² logically the freedom of choosing whether and when to have children should not stop after the birth, but should continue also in related decision-making, especially as breastfeeding influences the return of menstrual cycle and related hormonal changes. In general, analogically to Article 26 of European Convention on Human Rights and Biomedicine, the restrictions to the right to integrity might be justified, *inter alia*, for the protection of public health or the rights and freedoms of others.²⁸³

²⁷⁷ *Ibidem*, p. 680.

²⁷⁸ *Ibidem*, p. 682.

²⁷⁹ Article 2, section 1, letter (b) of Directive 2006/54/EC on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation, OJ L 204/23, 26.7.2006.

²⁸⁰ Case C-528/13, *Léger*, ECLI:EU:C:2015:288, para. 57-59.

²⁸¹ PEERS, Steve. *Article 3 – Right to the Integrity of the Person*. In: The EU Charter of Fundamental Rights: a commentary. Second edition. Hart Publishing, 2021, p. 45

²⁸² *Ibidem*, p. 43.

²⁸³ *Ibidem*, p. 55.

3.1.3. Manufacturers and distributors

3.1.3.1. Freedom to conduct a business

Article 16 protects the freedom of both natural and legal persons to engage in economic, business activity. Such activity covers wide range of sub-activities (notably freedom of contract, freedom of competition) and their various forms making use of disponible technical, economic and financial resources²⁸⁴. Due to the broad scope of the freedom, it includes also commercial speech, whose exercise falls also under freedom of expression under Article 11.²⁸⁵

The conduct of business activity is however not limitless. Other guiding principles and rights of the Charter provide limitations, that must be though always proportional to the pursued objectives²⁸⁶. CJEU even emphasises the social function of the freedom, which must be taken into account when interpreting and applying the principle.²⁸⁷ “Consequently, restrictions may be imposed on the exercise of the freedom to pursue a trade or profession, as on the exercise of the right to property, provided that the restrictions in fact correspond to objectives of general interest and do not constitute, in relation to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed.”²⁸⁸

What constitutes the substance might be framed only anecdotally: In *Alemo-Herron*²⁸⁹, allowing negotiating a collective treaty after the transfer of undertaking, without the transferee being able to participate on such negotiations, was considered as

²⁸⁴ FOREJTOVÁ, Monika. *Article 16. Freedom to Conduct a Business*. In: Treaty on the Functioning of the European Union ; Treaty on European Union ; Charter of Fundamental Rights of EU: a commentary. Wolters Kluwer. 2022, p. 1529.

²⁸⁵ Case C-157/14, *Neptune Distribution*, para 67.

²⁸⁶ Article 52 of the Charter.

²⁸⁷ Case C-157/14, *Neptune Distribution*, para 66.

²⁸⁸ Case C-151/17, *Swedish Match*, para 72.

²⁸⁹ Despite the scepticism of the jurisprudence towards the decision in *EVERSON, Michelle; GONÇALES, Rui C. Article 16 – Freedom to Conduct a Business*. In: The EU Charter of Fundamental Rights: a commentary. Second edition. Hart Publishing, 2021, p. 476.

able to infringe the essence of his right to conduct a business.²⁹⁰ In contrary, state's approval for major redundancies in *AGET Iraklis*, was not, as it was not *entirely excluding*.²⁹¹ In addition, CJEU concluded, that less restrictive measures would not apparently attain the objective of worker's protection as effectively, meaning the restriction was, in principle, proportionate.²⁹² Disproportionality was however caused by unclear conditions for such approval, rendering the measure unlawful.²⁹³ Mandatory information on packaging was in *Lidl* considered as proportionally restricting trader's freedom to conduct the business, as the information was supposed to protect consumers and again, there seemed to be no less restrictive measure to be adopted.²⁹⁴

3.1.3.2. Freedom of expression

Freedom of expression and information is affirmed by Article 11. Importance of the freedom recognizes CJEU when pointing out, that "*the fundamental right, guaranteed in Article 11 of the Charter, constitutes one of the essential foundations of a pluralist, democratic society, and is one of the values on which, under Article 2 TEU, the Union is founded.*"²⁹⁵ Although such emphasis has been put on the freedom of expression, it still falls under balancing, when different public interest comes into conflict with it²⁹⁶.

The freedom consists of all types of speech, including the commercial one.²⁹⁷ As CJEU states, "*the freedom is also protected under Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms, ... which applies, in particular, as is clear from the case-law of the European Court of Human Rights, to the dissemination by a business of commercial information, including in the form of*

²⁹⁰ Case C-426/11, *Alemo-Herron and Others*, ECLI:EU:C:2013:521, para 35.

²⁹¹ Case C-201/15, *AGET Iraklis*, ECLI:EU:C:2016:972, para 88.

²⁹² *Ibidem*, para 93.

²⁹³ *Ibidem*, para 100.

²⁹⁴ Case C-134/15, *Lidl*, ECLI:EU:C:2016:498, para. 37-39.

²⁹⁵ Joined Cases C-203/15 and C-698/15, *Tele2 Sverige*, ECLI:EU:C:2016:970, para. 93.

²⁹⁶ Article 52, section (1) of the Charter

²⁹⁷ WOODS, L., *op. cit.*, p. 347.

advertising.”²⁹⁸ “...it must be held that that freedom covers the use by a business, on packaging, labels and in advertising...”²⁹⁹

Legitimate reasons for a restriction are then enumerated in Article 10, section 2 of the European Convention and are also applicable in relation to restrictions of freedom of speech and information guaranteed by the Charter, while it is improbable, that the Charter would lay grounds for additional reason.³⁰⁰ Intensity of a review would then depend on the width of the margin of appreciation that varies based on the type of the speech, where for commercial restrictions, it will be wider than for political speech.³⁰¹ “*The discretion enjoyed by the competent authorities in determining the balance to be struck between freedom of expression and the objectives in the public interest which are referred to in Article 10(2) of the ECHR varies for each of the goals justifying restrictions on that freedom and depends on the nature of the activities in question. When a certain amount of discretion is available, review is limited to an examination of the reasonableness and proportionality of the interference. This holds true for the commercial use of freedom of expression in a field as complex and fluctuating as advertising.*”³⁰² However, the importance of the freedom requires, that for the interference, there must be “a pressing social need to interfere”.³⁰³ Both consumer protection and public health protection, as affirmed in Articles 35 and 38 of the Charter, are generally considered to be legitimate reasons for such interference, provided that the interference is not targeting the essence of the freedom and is proportional and not going beyond what is necessary.³⁰⁴

²⁹⁸ Case C-547/14, *Philip Morris*, para. 147.

²⁹⁹ Case C-157/14, *Neptune Distribution*, para 65.

³⁰⁰ WOODS, L., *op. cit.*, p. 355.

³⁰¹ *Ibidem*, p. 357.

³⁰² Case C-380/03, *Germany v Parliament and Council*, para 155, referring to case C-71/02 *Karner*, ECLI:EU:C:2004:181, para 51.

³⁰³ ECHR, *Monnat v Switzerland* of 21.09.1996 . [GC]. - 73604/01, para 55.

³⁰⁴ To that effect, see chapter 3.1.1.2 Health care, notably footnote 239 referring to case C-547/14, *Philip Morris*, para. 151.

3.2. Balancing the interests

In situation, where special regulation has been adopted on the basis of establishment and functioning of the internal market,³⁰⁵ further customization thriving for tailor-made regulation is due to regulator's duty to spare individual's fundamental rights – in case of BMS especially those reflected in empowering clauses of the primary law related to health and consumer protection – both possible and indispensable.³⁰⁶ From political point of view, it is even needed due to insufficiency of general protective tools (general consumer law or even general food law) in relation to special foods. At the same time, *“effective consumer protection has to differentiate between different consumer situations in order to find balance between consumer protection and unnecessary costs for business”*.³⁰⁷ In cases of complex free market constraints, the clash is not that simple and except of consumer or other form of protection challenging free conduct of business, other interests might be in stake³⁰⁸. During regulation of such conflicting rights and principles, Reich reminds, that even affected third parties must be taken into consideration.³⁰⁹ CJEU demonstrated this possible inclusion f.e. in aforementioned *UPC Telekabel Wien* case³¹⁰, where clash between protection of intellectual property and freedom to conduct a business of internet service providers in the end involved also interference with freedom of information of internet user's.

Building on previous analysis, it is clear that the starting point for balance assessment should be child's best interest, as provided in Article 24, section 2. However, it is absolutely insufficient to only bear in mind the principle. We must reflect it during balancing and incorporate it properly into the result. *“Indeed, in situations where different principles compete or conflict with one another, the best interest principle becomes decisive, bearing in mind that consideration of the best interests of the child must embrace*

³⁰⁵ Recital 1 of Directive 609/2013

³⁰⁶ Case C-376/98, *Germany v European Parliament and Council*, ECLI:EU:C:2000:544, para. 88.

³⁰⁷ SCHÜLLER, B., *op. cit.*, p. 141.

³⁰⁸ GARDE, A., *op. cit.*, p. 180.

³⁰⁹ REICH, N., *op. cit.*, p.140.

³¹⁰ Case C-314/12, *UPC Telekabel Wien*

short- as well as long-term considerations for the child.”³¹¹ The decisiveness though, in light of impact scaling of the principle, does not mean it should prevail over any other principle or right. Rather it shall be attributed a power to tip the scale in situation, where the result is uncertain enough. As pointed out by Jagielska and Jagielski already in 2012, it should be the courts who determine an adequate level of protection respecting fundamental rights provisions in relation to specificity of the party concerned.³¹² Unfortunately, the case-law have not substantially evolved yet, especially in relation to child’s best interest, though from some of the cases we might already derive conclusions.

Both health protection and protection of children (interconnected in case of infant protection in relation to breast-milk substitutes) are accepted as aims legitimising restriction on business conduct freedom and freedom of speech (also interconnected when speaking about product labelling and advertising restrictions). In cases of *Deutsches Weintor*³¹³, *Neptune Distribution*³¹⁴ and many of tobacco cases³¹⁵, high level of health protection was considered a legitimate aim. In *Dynamic Medien*³¹⁶, protection of children *per se* even legitimised national rule restricting trading freedom on internal market. CJEU noted in *Poland v Parliament and Council*, that EU legislature’s measures facilitating exercise of economic freedoms, shall also pursue protection of other fundamental interests.³¹⁷ Reconciliation of these competing principles should be guided by striking for a fair balance,³¹⁸ which occurs on the grounds of well-established four degree proportionality test – (1) legitimate aim is pursued by (2) appropriate measure, which is also (3) necessary, meaning it is not going beyond what is indispensable to achieve the aim, while there is not equally effective, less restrictive one, and the measure is also (4)

³¹¹ GARDE, A., *op. cit.*, p. 173

³¹² JAGIELSKA, M.; JAGIELSKI, M., *op. cit.*, p. 351

³¹³ Case C-544/10, *Deutsches Weintor*

³¹⁴ Case C-157/14, *Neptune Distribution*

³¹⁵ Cases C-380/03, *Germany v Parliament and Council*, C-547/14, *Philip Morris*, C-151/17, *Swedish Match*

³¹⁶ Case C-244/06, *Dynamic Medien*

³¹⁷ Case C-626/18, *Poland v Parliament and Council*, para. 53.

³¹⁸ Case C-157/14, *Neptune Distribution*, para. 75.

proportional *stricto sensu*, requiring the extent of restriction of one interest to be legitimised by similarly high or higher importance of the other.³¹⁹

We must also take into consideration specificity of the review of BMS legislation, which has been adopted by legislature in an area of wide discretion, as he had to undertake complex assessment involving political, economic and social choices.³²⁰ In such situation, CJEU calls for manifest inappropriacy for a provision to be considered unlawful.³²¹ In addition, the review is also limited when evaluating the legislature's findings of basic facts. These must be either sufficiently substantiated or, in case of absence of relevant data and research, their acceptance by the court is based on precautionary principle.³²²

Recital 22 acknowledges that “*There is scientific consensus that breast-milk is the preferred food for healthy infants.*” and refers to conclusions adopted by the Council on nutrition and physical activity³²³, which call for adequate breastfeeding support and promotion and acknowledges that breastfeeding is the best for health of mother and child.³²⁴ Even though this starting point could be considered “a basic fact”, it does not tell much about the adequacy of chosen scaling of protective restriction. It only substantiates protection of breastfeeding as measure suitable to pursue high level of health (and children) protection.

³¹⁹ FOREJTOVÁ, Monika. *Article 52. Scope of guaranteed rights*. In: Treaty on the Functioning of the European Union ; Treaty on European Union ; Charter of Fundamental Rights of EU: a commentary. Wolters Kluwer. 2022, p. 1644-1647.

³²⁰ BJORGE, Eirik; ZGLINSKI, Jan. *The principle of proportionality in EU law and its domestic application: ni tout à fait le même, ni tout à fait un autre*. Online. In: Research handbook on general principles in EU law: constructing legal orders in Europe. Edward Elgar Publishing, 2022, p. 199. Available at: <https://doi-org.ezproxy.is.cuni.cz/10.4337/9781784712389.00019>. [accessed on 2024-05-04].

³²¹ Case C-491/01, *British American Tobacco and Imperial Tobacco*, ECLI:EU:C:2002:741, para. 123.

³²² To that effect, see analysis in subchapter 3.1.1.2. *Health care*.

³²³ Council. *Council conclusions on nutrition and physical activity*. OJ C 213/1, 8.7.2014.

³²⁴ Proclamation is rather vague, as “child” in general means natural person aged between 0-18 years, exceeding the range of the term of young children aged from 0/1 to 3 years. Breastfeeding can also occasionally have short negative side-effects, mainly breastfeeding pain which can have numerous causes; see further KENT, Jacqueline C.; ASHTON, Elizabeth; HARDWICK, Catherine M.; ROWAN, Marnie K.; CHIA, Elisa S.; et al. *Nipple Pain in Breastfeeding Mothers: Incidence, Causes and Treatments*. Online. International Journal of Environmental Research and Public Health. 2015, vol. 12, issue 10, p. 12247-12263. Available at: <https://doi.org/10.3390%2Fijerph121012247>. [accessed on 2024-04-20].

In addition, the Recitals 22 and 23 refer to WHO Code, acknowledging its content and, *inter alia*, its implementation monitoring as one of actions adopted in EU Action Plan on Childhood Obesity 2014-2020. Though at the same time, specific factual and legal situation in the Union is mentioned, followed by acknowledgment of marketing having influence on parents and caregivers in relation to infant feeding. As special Union situation seems to stand in opposition to full adherence to the Code, claiming that marketing is indeed influential does not seem as specifying what special Union situation means, as it is a fact upon which the Code was built on and as such it could be considered as one of “basic facts” that fall out of court review. In addition, the recital does not even specify what kind of influence the marketing has, whether it is positive or negative one. In relation to previously mentioned Code, we might deduce that negative one is surely present. Though, one might guess that, especially due to specific situation in the Union, it can bring also positive consequences. F.e. advertising and labelling is part of competition process, which is driving innovation. Without possibility to communicate the innovations to consumer, there might be lower incentive in innovating the products, decreasing the overall benefit for the consumer.

Therefore, even though children and their health protection is a legitimate objective, it is unclear whether advertising and labelling restrictions are suitable to achieve it. Reference to the Code, and subsequently its content, could be taken as an undisputable basic fact, as it was adopted on global level and with major political consensus, even if legislator disturbs such understanding with insisting on special situation in the Union (without further explanation). In *Swedish Match*³²⁵, court acknowledged legislator’s wide discretion in taking decision based involving political, economic and social choices on complex assessments and did not asked for factual substantiation. Instead, the precautionary principle, as formulated in *Neptune*

³²⁵ Case C-151/17, *Swedish Match*

*Distribution*³²⁶, was sufficiently legitimising the adopted measures. From this perspective, advertising and labelling restrictions shall be considered suitable to attain the objective of health protection. Condition of necessity, however, must be examined from closer look. In order to do that, we may differentiate the restrictions into 4 groups:

- A) Important notice duty and other related positive informational duties: precise naming of the product, preparation and storage instructions, statements promoting breastfeeding, professional advice importance and information requirements in educational materials.
- B) General positive marketing (labelling, presentation and advertising) duties: clear distinction between infant and follow-on formula, providing information in such a way so as not to discourage breastfeeding.
- C) General negative marketing (labelling, presentation and advertising) duties: banned terms (humanised, maternalised, adapted and similar), nutrition and health claims ban on IF.
- D) Restriction of infant formula advertising in any form, except publications specialising in baby care and scientific publications, but even these are not allowed to idealise usage of infant formula.

In addition, we must decode the implicit logic behind the measures: By imposing mixture of positive and negative duties upon traders (and related subjects), consumers (parents and caregivers) will be able to make ~~more rational~~ better choices and hopefully won't buy the product inferior to breastfeeding when it is not necessary.³²⁷ The consumers

³²⁶ In *Neptune Distribution*, contestation of labelling restriction was rejected exactly because of insufficient evidence proving contrary – as European Food Safety Authority produced only uncertain opinions related to the contested measure. *A contrario*, if EFSA (or other relevant scientific body in relevant persuasive scale) provided enough scientific data undermining suitability of the measure, it might have been suspended by CJEU

³²⁷ Quite straight explanation was provided by delegate of Turkey during Committee meeting before Code adoption: “It was argued that mothers had a right to choose whether or not they wanted to breast-feed; no one would deny that, nor would anyone deny that a mother would always choose what was best for her baby, provided she was properly informed about the facts. However, if the expectant mother was showered with clever publicity and sometimes even free samples of breast-milk substitutes, she could not always be expected to make a wise decision in the best interests of the health

are thus assisted to choose in some way, liberated of some sort of inappropriate information and granted by important ones. In case of negative duties, it is uncertain, whether the otherwise provided information would lead them in wrong direction (and as such could be considered misleading and therefore violating UCPD directive) or, even if factually true, whether they could have negative objective effect on public health. We see, that already in this stage of the test, we cannot move forward without assessing the role of consumer protection. In former case, special ban particularizing general consumer protective measure, is not undesirable, as it is not extending existing limitations. In the latter, CJEU provided us with answer in *Philipp Morris* case³²⁸, where even a possibility of consumers interpretation as to the product related benefits or risk-reduction, legitimised a prohibition. However, contrary to *Philip Morris* tobacco case, where the approach was aiming at young non-smokers and dependant, addicted smokers' protection, we are not targeting same vulnerable consumers, even though parents and caregivers might be in relation to some specific messages considered particularly vulnerable (see Chapter 1). While the protection of children still plays a role (similarly to young people in relation to tobacco), these are not in similar position of consumers. Necessity of negative duties in current extent is therefore questionable as the commercial activity executed by the trader generally meets reasonable, circumspect and (relatively) well-informed³²⁹ caregiver. Legislator's discretion is though still supported by the fact, that his advertising possibilities are not banned absolutely, but there remain some channels to be used (baby care and scientific publications). In *Germany v Parliament and Council*³³⁰, even smaller advertising "breathing room" was considered as adequately proving legislator's effort not to go beyond what was necessary, as less restrictive measure would render it ineffective in achieving the objective. Same in *Dynamic Medien*, the restriction was considered as not going above what was necessary, as the trade of concerned goods

of her baby. The aim of the Code was precisely to protect mothers and future mothers from unethical marketing practices." (WHA34/1981/REC/3, *op. cit.*, p. 194)

³²⁸ Case C-547/14, *Philip Morris*

³²⁹ The question of proper information is in fact dependant also on positive duties

³³⁰ Case C-380/03, *Germany v Parliament and Council*

was not excluded absolutely but was limited to in person purchases. In addition, even the necessity of the measures itself is affected by public health protection related precautionary principle, by softening the threshold requirement.³³¹

The question of adequacy of information is, however, dependant also on positive duties, that are supporting directly the weaker party by lowering the informational asymmetry. Still, the scrutiny shall apply on whether current modulation is the best possible, as contrary to tobacco regulation, there are no requirements on placement, height or design of the statements. Even though it is not legislator's duty to introduce the best possible measure,³³² in relation to the scrutiny of necessity of harder measure (broad ban of IF advertising, except in specialised publications), question remains, whether the aim could not have been reached via better regulation of positive duties in concurrence with less strict negative duties. Taking into account specific consumer needs, caregiver mostly lacks awareness of his or her potential decision consequences, suggesting the adequate provision of information shall be the first remedy to be sought. Positive informational duties thus surely meet the condition of necessity.

Moving to proportionality test *stricto sensu*, business freedoms seem to come up short of delegitimising the adopted regulation pursuing high level of health and children protection supported by precautionary principle³³³ together with best interest of the child principle, given the importance of children's interests at stake³³⁴. As there is possible risk of women dropping breastfeeding, legislator chose cautious approach and tried to

³³¹ GOLDNER LANG, Iris. "Laws of Fear" in the EU: The Precautionary Principle and Public Health Restrictions to Free Movement of Persons in the Time of COVID-19. Online. European journal of risk regulation. 2023, vol. 14, issue. 1, s. 159-163. Available at: <https://doi.org/10.1017/err.2020.120>. [accessed on 2024-05-06].

³³² LOCK, Tobias. *Article 52 CFR. Scope and interpretation of rights and principles*. In: The EU treaties and the charter of fundamental rights: a commentary. NY: Oxford University Press, 2019, p. 2252.

³³³ INGLESE, Marco. *Please Smoke Your E-Cigarette Proportionally*. Online. European journal of health law. 2017, vol. 25, issue. 1, p. 82-83. Available at: <https://doi.org/10.1163/15718093-12510352>. [accessed on 2024-05-06].

³³⁴ WEATHERILL, Stephen. *Justification, proportionality, and consumer protection*. Online. In: Exceptions from EU free movement law: derogation, justification, and proportionality. Hart Publishing, 2016, p. 256. Available at: <https://doi.org/10.5040/9781474203067>. [accessed on 2024-05-04].

extensively limit the contact of such women with infant formula. In case they would still do, important notice together with other informational duties should support her rational and well-informed decision. However, these situations are not the only one happening on the market, as infant formulas are not bought only by breastfeeding women. Balancing exercise cannot therefore stop at pure business freedom vs. children health protection clash, as other interests are at stake – those of consumers *per se*.

Caregivers need proper information to make rational and informed choices and even though we have seen that in context of breastfeeding women, the interest in child's health protection seems to restrict other rights proportionally (these women can still find information in baby care publications or from a health care professional, while precaution in protection of child's best interest – healthy development – outweighs the scope of restriction), in relation to caregivers who are not breastfeeding anymore or at all, advertising and information limitation does not achieve its goal *stricto sensu*³³⁵. These latter consumers have different informational needs from those acting in favour of breastfed child. It must also be noted, that the two groups meet each other in specific situation of breastfeeding women, though seriously considering cessation of breastfeeding – she is in the same time in the need of information underlining (and explaining) the importance of breastfeeding, and also in the need of proper product information, so that she might eventually exercise her rights coming from consumer status – in such situation, she needs to be able to compare products and choose one best fitting her preferences concerning composition, price, producer etc.

In such case, different fundamental rights arise in relation to different stakeholders – while single father, adoptive parent or non-breastfeeding mother of an infant need to choose from products the market offers right after they become (sometimes sole) caregiver and thus they need to exercise their right to information, mother that is

³³⁵ Of course, it is achieving its goal overall, by protecting breastfed children, but proportionality between these two categories must be examined.

considering the transition from breast-milk towards formula, might bring in even her right to work and right to physical integrity, if these are motivational factors driving her choice. While the non-breastfeeding caregivers will be directed to start with formula most probably by health care professional, women might be in greyer situation, coming with the idea on their own and thus should be ideally directed to the paediatrician for a consultation. However, formulas are not products sold exclusively on prescription, which ideologically reflects the fact, that it is primary mother's right and responsibility to decide. Therefore, both these groups are in need of adequate information during purchasing process.

When balancing the clash between protection of (some) children's health and restriction on (some) consumers' informational right (and related need), fact remains that measures adopted by the legislator are suitable to achieve legitimate objective. However, the questionability of preferring negative duties over strengthening the positive ones increases, which subsequently influences the result of proportionality *stricto sensu* test too. Even though precaution still legitimises the ban of omnipresent general advertising according to Article 10 of BMS directive, general ban on nutrition and health claims on IFs in Article 8 does not seem to be of same importance in relation to public health protection.

Firstly, the ban does not differentiate between on-pack and off-pack communication. While claiming nutritional or health benefits of some components in public TV ad or an in-store banner seems to be able to attract attention of breastfeeding women too, their presence on-pack would influence only those being already further in consideration mode as a part of 2nd phase of consumer behaviour process.³³⁶ As general advertising is already forbidden by Article 10, Article 8 clearly targets on-pack communication (together with communication in baby care and scientific publications).

³³⁶ STANKEVICH, Alina. *Explaining the Consumer Decision-Making Process: Critical Literature Review*. Online. Journal of International Business Research and Marketing. 2017, vol. 2, issue 6, p. 10. Available at: <http://dx.doi.org/10.18775/jibrm.1849-8558.2015.26.3001>. [accessed on 2024-05-03].

Secondly, the argument in favour of the ban, that can be deduced from the fact, that components of IFs are always present (even though in different forms) in breast-milk, is insufficient. Even though highlighting some components might create impression, that the product is in some way better than breast-milk, such deficit could be less intrusively remedied by better explanatory positive information duties as to the composition of the product, highlighting not only importance of breast-feeding, but also its unreachability by any product of the category, while also design of the notice plays crucial role.³³⁷

Thirdly, it must be noted that Directive (EU) 2024/825³³⁸ of 28 February 2024 amended Directive 2005/29/EC, *inter alia*, by stating another forbidden misleading commercial practice in its annex: “*Presenting requirements imposed by law on all products within the relevant product category on the Union market as a distinctive feature of the trader’s offer.*”, which makes most of the nutrients (and related health claims) in relation to infant and follow-on formulas very much harder to claim, depending on assessment of distinctiveness of such claims.

Fourthly, usage of nutrition claims is preconditioned by scientific substantiation³³⁹. Possibility to claim such components is one of the reasons that drives innovation process, as distinctiveness of composition and its superiority, connected with its communication towards consumers with anticipation of influence on market position, is what pays for the research necessary for claiming such nutritional claims.

Fifthly, as composition of the formulas is governed by the BMS directive, it is exactly the voluntarily added substances that should serve consumers in their decision-making (together with cost of the product, specificities of the packaging, producers social

³³⁷ BIALKOVA S., *op. cit.*, p. 1049.

³³⁸ Directive (EU) 2024/825 of the European Parliament and of the Council of 28 February 2024 amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against unfair practices and through better information, OJ L, 6.3.2024.

³³⁹ Article 5 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, L 404/9, 30.12.2006.

responsibility, user experience etc.), but for the health of the child (and its best interest), it is the most important factor.

Sixthly, the ban is in systematic contradiction with allowed advertising requirement, to contain only information of scientific and factual nature. Current base for nutrition and health claim usage is in fact the scientific approach, as all of the claims must be approved by Commission³⁴⁰, while most probably undergoing assessment by EFSA. It is hard to imagine more scientific and factual information that is allowed to be in baby care and scientific publications.

3.2.1. Regulatory recommendations

From the analysis above, following recommendations arise:

1. In order to preventively strengthen the legitimacy of current regulation, the positive informational duties should be reformed so that they more effectively pursue the objective of the regulation – infant health protection via moderation of information flow that reaches the caregiver in the position of consumer. By such adaptation, the doubt about necessity of negative duties would be resolved and proportionality would be better guaranteed. Currently, if substantiated case was made manifestly proving low effect of BMS marketing on overall market growth of the category, the necessity of advertising ban would be undermined.³⁴¹ Instead, informational duties might be considered as equivalently or even more effectively achieving the same objective, but until their adoption, the protection level would be temporarily lower.

Therefore, the legislator should mainly ameliorate the design of important notice, taking inspiration f.e. from tobacco advertising regulation, since he already went

³⁴⁰ *Ibidem*, Article 8 and Article 17.

³⁴¹ WEATHERILL, S., 2016, *op. cit.*, p. 258.

for similarly intrusive measures as in the domain of tobacco. The situation compared to tobacco and tobacco products is even less dramatic, as size of packaging is in the formula market substantially bigger. Mainly the visibility and noticeability should be ensured, putting stress notably on consultancy with healthcare professional and on superiority of breastfeeding in every aspect (*sic!*) compared to formulas. Placement instruction for the notice should be also considered. The measure should reflect the behavioural and economical reality of consumers and producers, mainly by using adequately contrast interference (colour, size of the text), so that the notice would not sink between marketing text and composition list, relativising its actual impact on consumer choice.

2. Abolishment of nutrition and health claims ban seems to achieve better balance between different interests of various caregiver situations and business freedoms, as it is comprising lower risk for breastfeeding drop than general advertising, especially in connection with update on UCPD Directive, restricting *expressis verbis* distinctive claiming of components required by the law. Notifying consumer that most of the components are required by the law and distinguishing those components, together with aforementioned notice, that breast-milk always contains even more beneficial nutrients than the product, could put average consumer in more conscious position when understanding and assessing the nature of the product (rather than long list of chemical substances and nutritional values).
3. Currently, the regulatory rules in the domain of labelling, presentation and advertising are different for infant formula and follow-on formula, while specific legislative act for young child formulas does not exist, which is not following the evolution of WHO Code scope. Even though the regulator repeatedly acknowledges special situation in the Union and does not see a need in adopting rules for young child formulas, precautionary principle, as formulated in CJEU

case law, seems to be able to legitimise extension of some sort of regulation also beyond infant formulas. In fact, WHO recommendation to continue breastfeeding until 2 years of age counts with health benefits that breast-milk provides even after the period of 6 months of exclusive breastfeeding as complementary foods are introduced continuously up to the moment they fully replace breast-milk (ideally at the end of 2nd year of age or later)³⁴². The question however is, to what extent could precautionary and child's best interest principles (in the absence of scientific substantiation) legitimise similar restrictions in later stages. Even though the principle of formula marketing potentially causing breastfeeding drop still persists, mere fact, that after 1st year of life, cow's milk is generally accepted to be introduced into young child's diet, increases the importance of competition for BMS producers and distributors. Their (lawful) objective is not only persuading the consumers, that their YCFs are better than those of competition, but also that when choosing child's complex diet, they should prefer the formula over animal milk, if the child is not breastfed anymore. In addition, the impact on women on maternity leave in relation to their "labour market attractiveness" unfortunately deepens longer the maternity leave lasts, widening the gap between men and women.³⁴³ Negative effect of paternalistic³⁴⁴ advertising limitation trying to decrease the possibility of breastfeeding women thinking about switching to formula, seems to underestimate their decision-making capabilities and potentially hardening their labour market position.

4. Contrary to BMS Regulation, Infant FSMP Regulation is pursuing the objective of infants' health protection more clearly. Usage of the products by infants lacking relevant medical condition might be dangerous for their development. Because of

³⁴² WHO. *Infant and young child feeding*. 2023. Available at: <https://www.who.int/news-room/fact-sheets/detail/infant-and-young-child-feeding>. [accessed on 2024-05-03].

³⁴³ BATES, Lilian; HALL, Oliver; JAKIELA, Pamela. *Understanding the Impacts of Paid Maternity Leave on Women's Labor Market Outcomes*. Online. IZA DP No. 16565. 2023, p. 22. Available at: <https://ssrn.com/abstract=4619702>. [accessed on 2024-05-03].

³⁴⁴ INGLESSE, M., *op. cit.*, p. 85.

that, rules restricting advertising covering whole infant period are both necessary and proportionate (other form of solution – putting the products on mandatory prescription seem to be even more restrictive). Legitimacy is also strengthened by more complex positive informational duties.³⁴⁵

³⁴⁵ Article 5 of Infant FSMP Regulation

Conclusion

“It was thus essential to discuss together, so that countries could move forward in a spirit of solidarity in the search for greater justice.”³⁴⁶

Overall protection of infants under EU law was examined in this thesis. Infants were found to be protected through various legislative instruments, both directly and indirectly, ranging from general protective tools up to most specific ones. At the beginning, we analysed the nature of consumer protection law as one of the safeguards, trying to avoid unjust consequences of unfair situations. Notion of consumer and vulnerability was closely examined, both abstractly and concretely in relation to infants and their caregivers, while we focused on fluidity, limits and scaling of the latter, which is reflected in current legal instruments in distinguishing two categories of abstract consumers – the average and particularly vulnerable ones. Modern trend, so far in jurisprudence mainly, is focus on as much in-depth assessment of consumer as possible, taking into account all possible (but still relevant) causes of vulnerability, both internal and external. CJEU demonstrated willingness to such approach in few cases, although not in relation to particularly vulnerable consumers *per se* according to Article 5, section 3 of UCPD.

Infants were found to be very specific market stakeholders due to absence of legal capacity combined with their factual, rather than legal, particular vulnerability. Attributing them consumer status is improbable, thus disqualifying them from particularly vulnerable consumer protection too. General consumer law is empowering only their caregivers which, however, does not adequately reflect the dangers the infants might face. In addition, neither the caregivers are always *properly informed, reasonably*

³⁴⁶ Excerpt from a speech delivered by delegation of Algeria during Thirty-fourth World Health Assembly, Committee A on 20 May 1981 (*WHA34/1981/REC/3, op. cit.*, p. 190).

observant and circumspect. On the contrary, in some situations, where foreseeable and their group is clearly identifiable, they might be considered particularly vulnerable themselves, obtaining more tailor-made assessment when facing an unfair commercial practice. In relation to products intended for infants' usage, notably the age indication and invocation of health or safety connotations, and rarely a parent-related infant medical condition, are criteria allowing to meet necessary conditions of the definition.

Nevertheless, even higher level of consumer protection is not enough in situations, where infants potentially face very serious and difficult to grasp health consequences, especially when attributing such protection is incidental and thus harder to define because of necessary multidisciplinary approach, involving behavioural psychology, economy, legal assessment and medical evaluation. We observed that more specialised regulatory framework is in such cases indispensable, be it general product safety or food safety legislation, or even more detail oriented legislative acts. In order to extract protection for infants from these more general tools, diction of relevant clauses might sometimes be of importance due to infants' ineligibility for consumer status. While some legislative acts are potentially creating terminological confusion by sticking to term "consumers" (notably Food Imitating Products Directive and General Product Safety Regulation), that could lead to lower level of protection for infants, the gap might be overlapped by teleological and systematic interpretation.

Most specialised legislative acts mentioned and analysed are setting highly exact rules for composition and safety (notably Toy Safety Directive and both BMS and Infant FSMP Regulations), though we excluded further evaluation of proportionality of these clauses due to their clear scientific substantiation, whereas it is highly improbable, that potential unsubstantiated excess of such restrictions would beat precautionary principle adopted by CJEU in relation to protection of public health due to regulator's broad discretion. Even if it did, for such counterargument a scientific assessment would be necessary instead of a legal one. For examination of conformity with the Charter, we

therefore narrowed the scope to clauses restricting advertising and labelling in relation to breast-milk substitutes.

Before moving to conformity evaluation exercise, we described not only the relevant clauses of BMS Regulation, but also its roots, both historical and international in order to reveal reasons for its adoption. Even though WHO Code for Marketing of Breast-milk Substitutes was adopted in a spirit of necessity, symbolically demonstrated by almost unanimous vote for its adoption, European BMS regulatory framework did not neither copy the Code literally, neither it took it as primary source of legislation. Instead, legislator “went his own way”, stressing from the first directive tackling the issue³⁴⁷, adopted 20 years after the adoption of the Code, the “particular legal and factual situation in the Community”. The distinctiveness of EU legislation has become even more visible in last decade, when WHO clarified the scope of the Code, extending the rules in general to all formulas intended for children until 36 months of age. However, from the examination of Committee meeting records before the Code adoption, it was well visible that the scope was unclear during that time already. Current BMS Regulation even lacks, compared to its predecessor, direct reference and adherence to the Code, limiting even more the possibility to interpret it in light of the Code, as the Code did not have a binding effect right since its initial adoption, as it has been adopted in the form of recommendation.

As we must consider BMS regulatory framework mostly independently, we concentrated in last part on evaluation of conformity of the BMS Regulation advertising and labelling clauses with the Charter, bearing in mind that stronger intervention comes hand in hand with heavier effect on others’ fundamental rights and freedoms. It was therefore necessary to find proportionality between different leading rights and principles, while the assessment was based mainly on CJEU case-law combined with opinions of jurisprudence, which were firstly analysed in relation to each separate concerned right or

³⁴⁷ Commission Directive 91/321/EEC

freedom guaranteed by the Charter, while the assessment aimed at highlighting those aspects, that were of use in subsequent balancing exercise.

Imminent clash between protection of child's best interest and maintenance of high level of public health protection (*in concreto* through protection of infants' health) on one side and freedom of expression and freedom to conduct a business on the other was found to be generally strongly favouring the uphold of current BMS advertising and labelling restrictions. Legislator enjoying wide discretion in concerned area, supported by CJEU's well established precautionary principle in relation to public health protection, does not necessarily require a minimal factual substantiation and even if it was not the case, BMS Regulation does contain some sort of it, even though some reservations were formulated (especially in relation to vague statement of specific Union situation). After conducting proportionality test, we concluded, that adopted measures are necessary and in first simplified comparison they withstand also the proportionality test *stricto sensu*.

Secondly the involvement of caregivers, whose interests are at stake too, revealed which areas of BMS Regulation should be better assessed. While absence of most of the restrictions would probably have very serious negative effect on public health, their legitimacy withstands even the interference with caregiver right to information, which in BMS case specifies general request for high level of consumer protection. At the same time, current modulation of advertising ban on IFs protects infant in its most vulnerable phase, which legitimises legislator's choice to limit incentivisation of women to cease breastfeeding, even from noble reasons (such as return to work). However, there remains a question mark upon extension of the restrictions to other age categories. While after 1st year of life, the addition of cow's milk as a competitor to the formula, together with slowly decreasing importance of breast-milk and potential increasing subjective importance for woman to return to work seem to change the equation to the extent, that the precautionary principle might not be enough to legitimise the same extent of restriction as for the IFs, the FOFs might continue in the footsteps of its predecessors, if

legislator sees such need. In such case, however, balancing exercise with women's rights should be conducted again.

To support the legitimacy of status quo BMS Regulation, we suggested abolishment of nutrition and health claims ban on IF packaging as it would not have to pose the same high risk as general public advertising and it would better serve the innovation process, beneficial both for producers and consumers. In addition, we also called for more practical and effective positive informational duties, as those currently in force are neither regulated as to their visibility, nor placement and in the context of informational overdose, that the formula packaging contains, these most important measures for informed choice seem to lack relevance, undermining necessity of even more intrusive absolute advertising ban.

The objective of this thesis was to contribute to still evolving discussions about regulating infant feeding by striving for complex legal assessment, in words of a physician and microbiologist Walther Hesse: *"...it is not the monopoly of only one professional guild, but the duty of every man, who feels drawn to it, whether he is a doctor, hygienist or chemist, to contribute to the life and health of infants in his own manner..."*³⁴⁸ We conclude that current EU regulatory framework in relation to infant protection is legitimate and when assessing the conformity with the Charter, generally both necessary and proportionate. Still, terminological and substantive changes were suggested to strengthen both the legitimacy and level of protection itself.

³⁴⁸ VÖGELE, J.; MARTIN, M.; RITTERSHAUS, Luisa, *op. cit.*, p. 134; citing Walther HESSE, *"Ueber einen neuen Muttermilchersatz: Pfund's Säuglingsnahrung"*. In: Zeitschrift für Hygiene und Infektionskrankheiten. 1900, vol. 35, p. 439-494.

List of abbreviations

BMS	Breast-milk Substitute
EFSA	European Food Safety Authority
ESC	European Social Charter
FOF	Follow-on Formula
FSMP	Food for Special Medical Purposes
GPSD	General Product Safety Directive
GPSR	General Product Safety Regulation
IF	Infant Formula
IOCU	International Organisation of Consumers Unions
UCPD	Unfair Commercial Practices Directive
WHA	World Health Assembly
WHO	World Health Organization
WHO Code	The International Code on Marketing of Breast-milk Substitutes
YCF	Young Child Formula

Bibliography

1. Books

BOOM, W. H. van; GARDE, Amandine; AKSELI, Orkun N. *The European unfair commercial practices directive: impact, enforcement strategies and national legal systems*. Ashgate, 2014, 271 p. ISBN: 978-1-4724-2340-5.

BUREŠOVÁ, Jitka; POSPÍŠILOVÁ, Marie; UNGERMAN, Otakar; DĚDKOVÁ, Jaroslava; JURSOVÁ, Jitka; BERKI, Jan. *Online marketing communication targeting school age children*. Masaryk University, 2023, 383 p. ISBN: 978-80-280-0303-6.

DEVENNEY, James a KENNY, Mel. *European consumer protection: theory and practice*. Online. Cambridge University Press, 2012, 462 p. ISBN: 1-139-36604-1. Available at: <https://search.ebscohost.com/login.aspx?direct=true&db=e000xww&AN=443656&lang=cs&site=ehost-live>. [accessed on 2024-04-26].

DVOŘÁK, Jan; ŠVESTKA, Jiří; ZUKLÍNOVÁ, Michaela; BERAN, Karel; ELISCHER, David et al. *Substantive Civil Law 1*. Second, updated edition. Wolters Kluwer, 2016, 436 p. ISBN: 978-80-7552-187-3.

HAMILTON, Kathy; DUNNETT, Susan; PIACENTINI, Maria. *Consumer Vulnerability: Conditions, Context and Characteristics*. Online. 2015, 235 p. ISBN: 9780203797792 Available at: <https://ebookcentral.proquest.com/lib/cuni/detail.action?docID=3570276>. [accessed on 2024-04-26].

HOWELLS, Geraint; TWIGG-FLESNER, Christian; WILHELMSSON, Thomas. *Rethinking EU Consumer Law*. Online. 1st edition. Routledge, 2017, 356 p. ISBN: 9781315164830. Available at: <https://doi.org/10.4324/9781315164830>. [accessed on 2024-04-28].

HOWELLS, Geraint; NORDHAUSEN Annette; PARRY Deborah; TWIGG-FLESNER Christian. *The Yearbook of Consumer Law*. Ashgate publishing, 2007, reissued by Routledge, 2018, 449 p. ISBN: 978-0-429-43086-2.

RIEFA, Christine; SAINTIER, Severine. *Vulnerable Consumers and the Law*. 1st edition. Routledge, 2021, 280 p. ISBN: 9780367555184.

KELLERBAUER, Manuel; KLAMERT, Marcus; TOMKIN, Jonathan. *The EU treaties and the charter of fundamental rights: a commentary*. NY: Oxford University Press, 2019, 2512 p. ISBN: 9780198846925.

KOUTRAKOS Panos; SHUIBHNE, Niamh N.; SYRPIS, Phil. *Exceptions from EU free movement law: derogation, justification, and proportionality*. Hart Publishing, 2016, 318 p. ISBN: 978-1-47420-306-7. Available at: <https://doi.org/10.5040/9781474203067>. [accessed on 2024-05-04].

LECZYKIEWICZ, Dorota; WEATHERILL, Stephen. *The images of the consumer in EU law: legislation, free movement and competition law*. Oxford: Hart Publishing, 2016, 488 pages. ISBN: 978-1-84946-544-1.

NAIRN, Agnes, HANG, Haiming. *Advergaming. It's not child's play*. Online. Online. Family and Parenting Institute, 2012, 22 p. Available at: https://www.agnesnairn.co.uk/policy_reports/advergaming-its-not-childs-play.pdf. [accessed on 2024-04-26].

OECD. *National Accounts at a Glance 2013*. Online. OECD Publishing, 2013, 111 p. ISBN: 9789264335318. Available at: https://doi.org/10.1787/na_glance-2013-en. [accessed on 2024-04-26].

POSNER, Richard. *Regulation (Agencies) versus Litigation (Courts): an Analytical Framework*. Online. In: *Regulation vs. Litigation: Perspectives from Economics and Law*. University of Chicago Press, 2009, p. 11-26. ISBN: 978-0-226-43218-2. Available at: <http://www.nber.org/chapters/c11956>. [accessed on 2024-04-29].

PEERS, Steve; HERVEY, Tamara K.; KENNER, Jeff; WARD, Angela. *The EU Charter of Fundamental Rights: a commentary*. Second edition. Hart Publishing, 2021, 2016 p. ISBN: 978-1509933471.

RICHTER, Judith C. *International regulation of transnational corporations: The infant food debate*. PhD Thesis. Amsterdam University. 2001, 183 p. Available at: <https://hdl.handle.net/11245/1.193514>. [accessed on 2024-04-29].

SOKOL, Ellen J. *The Code handbook: a guide to implementing the International Code of Marketing of Breastmilk Substitutes*. 2nd edition. IBFAN – ICDC, 2005, 395 p. ISBN: 983-9075-13-6. Available at: <https://www.babymilkaction.org/wp-content/uploads/2023/06/The-Code-Handbook-2005-with-appendices.pdf>. [accessed on 2024-04-29].

STALFORD, Helen. *Children and the European Union : Rights, Welfare and Accountability*. Hart Publishing, 2012, p. 278. ISBN 9781841137650. Available at:

<https://search.ebscohost.com/login.aspx?direct=true&db=e000xww&AN=531169&lang=cs&site=ehost-live>. [accessed on 2024-05-06].

TOMÁŠEK, Michal; ŠMEJKAL, Václav. *Treaty on the Functioning of the European Union ; Treaty on European Union ; Charter of Fundamental Rights of EU: a commentary*. Wolters Kluwer. 2022, 1661 p. ISBN: 978-80-7676-508-5.

TOMÁŠEK, Michal; TÝČ, Vladimír et al. *European Union Law*. 3rd edition. Leges, 2021, 512 p. ISBN: 978-80-7502-491-6.

ZIEGLER, Katja S.; NEUVONEN, Päivi J.; MOREANO-LAX, Violeta. *Research handbook on general principles in EU law: constructing legal orders in Europe*. Edward Elgar Publishing, 2022, 656 p. ISBN: 9781784712389. Available at: <https://doi-org.ezproxy.is.cuni.cz/10.4337/9781784712389.00019>. [accessed on 2024-05-04].

ZWINGER, Antonín; ŠKARDA, Martin. *Obstetrics*. 1. edition. Galén, 2004, 532 p. ISBN: 80-7262-257-9.

2. Articles

ALGARVIO, Susana; LEAL, Isabel. *PARENTAL CONCERNS DEFINITION: A SYSTEMATIC LITERATURE REVIEW*. Online. *Psicologia, Saúde & Doença*. 2016, vol. 17, issue 3, p. 423-440. <http://dx.doi.org/10.15309/16psd170310>. [accessed on 2024-04-27].

ANDERSON Phil; DAVIDSON Gavin; DOHERTY Francess; HANNA Heather; HARPER Colin, et al. *Legal capacity, developmental capacity, and impaired mental capacity in children under 16: Neurodevelopment and the law in Northern Ireland*. Online. *International Journal of Law and Psychiatry*. 2023, vol. 87, issue 101872, p. 3. Available at: <https://doi.org/10.1016/j.ijlp.2023.101872>. [accessed on 2024-04-26].

BABIĆ, Anđela R. *The Socio-Cultural Context of Breastfeeding in the Nineteenth and Twentieth Centuries*. Online. *Collegium Antropologicum*. 2020, vol. 44, issue 4, p. 245-253. Available at: <https://doi.org/10.5671/ca.44.4.8>. [accessed on 2024-04-29].

BADGAIYAN, Anantjyoti J.; VERMA, Anshul; DIXIT, Saumya. *Impulsive buying tendency: measuring important relationships with a new perspective and an indigenous scale*. Online. *IIMB Management Review*. 2016, vol. 28, issue 4, p. 186-

199. Available at: <http://dx.doi.org/10.1016/j.iimb.2016.08.009>. [accessed on 2024-04-27].

BATES, Lilian; HALL, Oliver; JAKIELA, Pamela. *Understanding the Impacts of Paid Maternity Leave on Women's Labor Market Outcomes*. Online. IZA DP No. 16565. 2023, p. 22. Available at: <https://ssrn.com/abstract=4619702>. [accessed on 2024-05-03].

BAYNE, Tim. *When do humans become conscious – in the womb or after birth?* Online. In: BigThink.com 19.5.2023. Available at: <https://bigthink.com/the-well/human-consciousness-womb-after-birth/>. [accessed on 2023-12-02].

BAYNE, Tim; FROHLICH Joel; CUSACK Rhodri; MOSER Julia; NACI Lorina. *Consciousness in the cradle: on the emergence of infant experience*. Online. Trends in Cognitive Sciences. 2023, Vol. 27, Issue 12, p. 1135-1149. Available at: <https://doi.org/10.1016/j.tics.2023.08.018>. [accessed on 2024-04-26].

BENN, Yeal; WEBB, Thomas L.; CHANG, Betty P.I.; REIDY, John. *What information do consumers consider, and how do they look for it, when shopping for groceries online?* Online. Appetite. 2015, vol. 89, p. 265-273. Available at: <https://doi.org/10.1016/j.appet.2015.01.025>. [accessed on 2024-05-01].

BENTON, Madeleine; SALTER, Amy; TAPE, Nicole; et al. *Women's psychosocial outcomes following an emergency caesarean section: A systematic literature review*. Online. BMC Pregnancy Childbirth. 2019, vol. 19, no. 535. Available at: <https://doi.org/10.1186/s12884-019-2687-7>. [accessed on 2024-04-27].

BIALKOVA Svetlana; van TRIJP, Hans. *What determines consumer attention to nutrition labels?* Online. Food Quality and Preference. 2010, vol. 21, issue 8, p. 1042-1051. Available at: <https://doi.org/10.1016/j.foodqual.2010.07.001>. [accessed on 2024-05-01].

BOTH, Denise. *The International Code of Marketing of Breastmilk Substitutes: History, Content, and Significance*. Online. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2018, vol. 61, p. 1008–1011. Available at: <https://doi.org/10.1007/s00103-018-2765-4>. [accessed on 2024-04-29].

BUNIK, Maya; SHOBE, Patricia; O'CONNOR, Mary E.; BEATY, Brenda; LANGENDOERFER, Sharon; CRANE Lori; KEMPE, Allison. *Are 2 Weeks of Daily Breastfeeding Support Insufficient to Overcome the Influences of Formula?*. Online. Academic Paediatrics. 2010, vol. 10, issue 1, p. 21-28. Available at: <https://doi.org/10.1016/j.acap.2009.09.014>. [accessed on 2024-04-27].

CARRUTHERS, Peter. *Human Creativity: Its Cognitive Basis, Its Evolution, and Its Connections with Childhood Pretence*. Online. The British Journal for the Philosophy of Science. 2002, vol. 53, issue 2, p. 225-249. Available at: <https://www.jstor.org/stable/3541765>. [accessed on 2024-04-26].

CLARK, Andrew E.; DIENER, Ed; GEORGELLIS, Yannis; LUCAS, Richard E. *Lags and Leads in Life Satisfaction: A Test of the Baseline Hypothesis*. Online. The Economic Journal. 2008, vol. 118, issue 529, p. F222-F243. Available at <https://www.jstor.org/stable/20108833>. [accessed on 2024-04-27].

CLEMENT, Sarah. *Psychological aspects of caesarean section*. Online. Best Practice & Research Clinical Obstetrics & Gynaecology. 2001, vol. 15, issue 1, p. 109-126. Available at: <https://doi.org/10.1053/beog.2000.0152>. [accessed on 2024-04-27].

COMPANY-MORALES, Miguel; ZAFRA APARICI, Eva; CASADÓ, Lina; ALARCÓN MONTENEGRO, Cristina; ARREBOLA, Juan P. *Perception and Demands of Pregnant and Breastfeeding Women Regarding Their Role as Participants in Environmental Research Studies*. Online. International journal of environmental research and public health. 2021, vol. 18, issue 8, p. 1-3. Available at: <https://doi.org/10.3390/ijerph18084149>. [accessed on 2024-04-26].

DE ROSSO, Sofia; DUCROT, Pauline; CHABANET, Claire; NICKLAUS, Sophie; SCHWARTZ, Camille. *Increasing Parental Knowledge About Child Feeding: Evaluation of the Effect of Public Health Policy Communication Media in France*. Online. Frontiers in public health. 2022, vol. 10, no. 782620, p. 2. Available at: <https://doi.org/10.3389/fpubh.2022.782620>. [accessed on 2024-04-27].

DHAS, Brightlin N.; CHACKO, Shoba M.; DAVID SOLOMON, Vince S.; SRIRAM, Vimal. *Parents' awareness, knowledge, and experiences of play and its benefits in child development: A systematic review protocol*. Online PloS one. 2022, vol. 17, issue 9. Available at: <https://doi.org/10.1371/journal.pone.0274238>. [accessed on 2024-04-27].

EDWARDS, Ben; CLARKE, Valerie. *The Psychological Impact of a Cancer Diagnosis on Families: The Influence of Family Functioning and Patients' Illness Characteristics on Depression and Anxiety*. Online. Psycho-Oncology. 2004, vol. 13, p. 562-576. Available at: <https://doi.org/10.1002/pon.773>. [accessed on 2024-04-26].

FOMON, Samuel J. *Infant Feeding in the 20th Century: Formula and Beikost*. Online. The Journal of Nutrition. 2/2001, vol. 131, issue 2, p. 409S-420S. Available at: <https://doi.org/10.1093/jn/131.2.409S>. [accessed on 2024-04-29].

GAREL, Micheline; LELONG, Nathalie; KAMINSKI, Monique. *Follow-up study of psychological consequences of caesarean childbirth*. Online. Early Human Development. 1988, vol. 16, issues 2–3, p. 271-282. Available at: [https://doi.org/10.1016/0378-3782\(88\)90108-9](https://doi.org/10.1016/0378-3782(88)90108-9). [accessed on 2024-04-27].

GINSBURG, Kenneth, R; the COMMITTEE ON COMMUNICATIONS; the COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH. *The Importance of Play in Promoting Healthy Child Development and Maintaining Strong Parent-Child Bonds*. Online. Paediatrics. 2007, vol. 119 issue 1, pages 182–191. Available at: <https://doi.org/10.1542/peds.2006-2697>. [accessed on 2024-04-27].

GOGOI, Bidyut J. *Do impulsive buying influence compulsive buying?* Online. Academy of Marketing Studies Journal. 2020, vol. 24, issue 4, p. 1–15. Available at: <https://www.abacademies.org/articles/do-impulsive-buying-influence-compulsive-buying-9531.html>. [accessed on 2024-04-27].

GOLDNER LANG, Iris. “*Laws of Fear*” in the EU: *The Precautionary Principle and Public Health Restrictions to Free Movement of Persons in the Time of COVID-19*. Online. European journal of risk regulation. 2023, vol. 14, issue. 1, s. 141-164. Available at: <https://doi.org/10.1017/err.2020.120>. [accessed on 2024-05-06].

GUÉGEN, Daniel; MARISSSEN, Vicky. *Science-based and evidence-based policy-making in the European Union: coexisting or conflicting concepts?* Online. Bruges Political Research Papers. 2022, vol. 88, p. 5-7, 26-27. Available at: https://www.coleurope.eu/sites/default/files/research-paper/wp88%20Marisen_Guegen.pdf. [accessed on 2024-04-29].

HERNANDEZ, Raquel G; THOMPSON, Darcy A.; CHENG, Tina L.; SERWINT, Janet R. *Early-Childhood Obesity: How Do Low-Income Parents of Preschoolers Rank Known Risk Factors?* Online. Clinical Paediatrics. 2012, vol. 51, issue 7, p. 663-670. Available at: <https://doi.org/10.1177/0009922812440841> . [accessed on 2024-04-27].

HUANG, Yi; LIU, Yu; YU, Xiao-Yan; ZENG, Tie-Ying. *The rates and factors of perceived insufficient milk supply: A systematic review*. Online. Maternal & Child

Nutrition, 2021, vol. 18, issue 1, p. 1. <https://doi.org/10.1111/mcn.13255>. [accessed on 2024-04-27].

INGLESE, Marco. *Please Smoke Your E-Cigarette Proportionally*. Online. European journal of health law. 2017, vol. 25, issue. 1, p. 75-87. Available at: <https://doi.org/10.1163/15718093-12510352>. [accessed on 2024-05-06].

JASPAL, Rusi; LOPES, Barbara; LOPES, Pedro; HUBERT, Marco. *Predicting social distancing and compulsive buying behaviours in response to COVID-19 in a United Kingdom sample*. Online. Cogent Psychology. 2020, vol. 7, issue 1, p. 12. Available at: <https://doi.org/10.1080/23311908.2020.1800924>. [accessed on 2024-04-27].

KENT, Jacqueline C.; ASHTON, Elizabeth; HARDWICK, Catherine M.; ROWAN, Marnie K.; CHIA, Elisa S.; et al. *Nipple Pain in Breastfeeding Mothers: Incidence, Causes and Treatments*. Online. International Journal of Environmental Research and Public Health. 2015, vol. 12, issue 10, p. 12247-12263. Available at: <https://doi.org/10.3390%2Fijerph121012247>. [accessed on 2024-04-20].

LIKHAR Akanksha; PATIL Manoj S. *Importance of Maternal Nutrition in the First 1,000 Days of Life and Its Effects on Child Development: A Narrative Review*. Online. Cureus. 2022, vol. 14, issue 10. Available at: <https://doi.org/10.7759/cureus.30083>. [accessed on 2024-04-26].

LIU, Pei; HE, Jinglun; LI, Aimei. *Upward social comparison on social network sites and impulse buying: A moderated mediation model of negative affect and rumination*. Online. Computers in Human Behavior. 2019, vol. 96, p. 133-140. Available at: <https://doi.org/10.1016/j.chb.2019.02.003>. [accessed on 2024-04-27].

LONARDO, Luigi. *The best interests of the child in the case law of the Court of Justice of the European Union*. Online. Maastricht Journal of European and Comparative Law. 2022, vol. 29, issue 5, p. 596-614. Available at: <https://doi.org/10.1177/1023263X221144829>. [accessed on 2024-04-30].

MARTIN, Camilia; LING, Pei-Ra; BLACKBURN, George. *Review of Infant Feeding: Key Features of Breast-milk and Infant Formula*. Online. Nutrients. 2016, vol. 8, issue 5, p. 1. Available at: <https://doi.org/10.3390/nu8050279>. [accessed on 2024-04-26].

MESIBOV, G. B.; SCHROEDER, C. S.; WESSON, L. *Parental Concerns About Their Children*. Online. Journal of Paediatric Psychology. 1977, vol. 2, issue 1, pages

13–17. Available at: <https://doi.org/10.1093/jpepsy/2.1.13>. [accessed on 2024-04-27].

MULDER, Jotte. *Responsive Adjudication and the 'Social Legitimacy' of the Internal Market*. Online. European law journal: review of European law in context. 2016, vol. 22, issue 5, p. 597-620. Available at: <https://doi.org/10.1111/eulj.12205>. [accessed on 2024-04-25].

NAVRÁTIL, Petr; ŠMEJKAL, Václav. *Every consumer or eu citizen only: who benefits from consumer protection law?* In: AUC Iuridica. Charles University. 2013, vol. 59, no. 2, p. 67-77.

NELSON, Katherine S.; KUSHLEV, Kostadin; LYUBOMIRSKY, Sonja. *The pains and pleasures of parenting: when, why, and how is parenthood associated with more or less well-being?* Online. Psychological Bulletin. 2014, vol. 140, issue 3, p. 846–895. Available at: <https://doi.org/10.1037/a0035444>. [accessed on 2024-04-27].

PERNER Josef; DIENES Zoltán. *Developmental aspects of consciousness: How much theory of mind do you need to be consciously aware?* Online. Consciousness and Cognition. 2003, vol. 12, issue 1, p. 63-82. Available at: [https://doi.org/10.1016/S1053-8100\(02\)00010-7](https://doi.org/10.1016/S1053-8100(02)00010-7). [accessed on 2024-04-26].

RINGOLD, Debra Jones. *Social criticisms of target marketing: Process or product?* Online. American Behavioral Scientist. 1995, vol. 38, issue 4, p. 578-592. Available at: <https://doi.org/10.1177/0002764295038004008>. [accessed on 2024-04-26].

RINGOLD, Debra Jones. *Vulnerability in the Marketplace: Concepts, Caveats, and Possible Solutions*. Online. Journal of Macromarketing. 2005, vol. 25, issue 2, p. 202-214. Available at: <https://doi.org/10.1177/0276146705281094>. [accessed on 2024-04-26].

ROBERT, Emmanuelle; COPPIETERS, Yves; SWENNEN, Béatrice; DRAMAIX, Michéle. *The Reasons for Early Weaning, Perceived Insufficient Breast-milk, and Maternal Dissatisfaction: Comparative Studies in Two Belgian Regions*. Online. International scholarly research notices. 2014, no. 678564, p. 6. Available at: <https://doi.org/10.1155/2014/678564>. [accessed on 2024-04-27].

ROCHAT, Philippe. *Object manipulation and exploration in 2- to 5-month-old infants*. Online. Developmental Psychology. 1989, vol. 25, issue 6, p. 871–884. Available at: <https://doi.org/10.1037/0012-1649.25.6.871>. [accessed on 2024-04-29].

ROMANOS-NANCLARES, Andrea; ZAZPE, Itziar; SANTIAGO, Susana; MARÍN, Lucía; RICO-CAMPÀ, Anaïs; MARTÍN-CALVO, Nerea. *Influence of Parental Healthy-Eating Attitudes and Nutritional Knowledge on Nutritional Adequacy and Diet Quality among Preschoolers: The SENDO Project*. Online. *Nutrients*. 2018, vol. 10, no. 1875, p. 12. Available at: <https://doi.org/10.3390/nu10121875>. [accessed on 2024-04-27].

ROWOLD, Katharina. „If We Are to Believe the Psychologists ...": *Medicine, Psychoanalysis and Breastfeeding in Britain, 1900–55*. Online. *Medical History*. 2018, vol. 63, issue 1, p. 61-81. Available at: <https://doi.org/10.1017/mdh.2018.63>. [accessed on 2024-04-29].

SPOTSWOOD, Fiona; NAIRN, Agnes. *Children as vulnerable consumers: a first conceptualisation*. Online. *Journal of marketing management*. 2016, vol. 32, issue 3-4, p. 211-229. Available at: <https://doi.org/10.1080/0267257X.2015.1107616>. [accessed on 2024-04-29].

SANDALL, Jane; TRIBE, Rachel M.; AVERY, Lisa; MOLA, Glen; VISSER, Gerard H. A.; et al. *Short-term and long-term effects of caesarean section on the health of women and children*. Online. *The Lancet*. 2018, vol. 392, issue 10155, p. 1349-1357. Available at: https://www.researchgate.net/publication/328241536_Short-term_and_long-term_effects_of_caesarean_section_on_the_health_of_women_and_children. [accessed on 2024-04-27].

STANKEVICH, Alina. *Explaining the Consumer Decision-Making Process: Critical Literature Review*. Online. *Journal of International Business Research and Marketing*. 2017, vol. 2, issue 6, p. 7-14. Available at: <http://dx.doi.org/10.18775/jibrm.1849-8558.2015.26.3001>. [accessed on 2024-05-03].

STEVENS, Emily E.; PATRICK, Thelma E.; PICKLER, Rita. *A History of Infant Feeding*. Online. *Journal of Perinatal Education*. 2009, vol. 18, issue. 2, p. 32–39. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2684040/>. [accessed on 2024-04-29].

STRAUGHAN, Paulin T.; XU, Chengwei. *Parents' Knowledge, Attitudes, and Practices of Childhood Obesity in Singapore*. Online. *SAGE Open*. 2022, vol. 12, issue 4, p. 8. Available at: <https://doi.org/10.1177/21582440221144436>. [accessed on 2024-04-27].

SZILÁGYI, Dániel. *Empowering Consumers: Towards a broader interpretation of vulnerable consumer concept in the European Union*. Online. Hungarian Journal of Legal Studies. 2022, vol 63, issue 3, p. 279–293. Available at: <https://doi.org/10.1556/2052.2022.00337>. [accessed on 2024-04-26].

VÖGELE, Jörg; MARTIN, Michael; RITTERSHAUS, Luisa. *Artificial Infant Nutrition in the Context of Science and Economy in the Late Nineteenth and Early Twentieth Centuries*. Online. Food and History. 2014, vol. 2, p. 119–135. Available at: <https://doi.org/10.1484/J.FOOD.5.108965>. [accessed on 2024-04-29].

WADDINGTON, Lisa. *Reflections on the Protection of „Vulnerable“ Consumers under EU Law*. Online. Maastricht Faculty of Law Working Paper. 2013, issue 2. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2532904. [accessed on 2024-04-28].

WEATHERILL, Stephen. *Consumer protection under EU law ‘is not absolute’: yes, but be careful*. Online. European review of contract law: ERCL. 2012, vol. 8, issue 2, p. 221-233. Available at: <https://doi.org/10.1515/ercl-2012-0221>. [accessed on 2023-11-11].

WILLMAN-IIVARINEN, Hanna. *The future of consumer decision making*. Online. European Journal of Futures Research. 2017, vol. 5, issue 14, p. 3. Available at: <https://doi.org/10.1007/s40309-017-0125-5>. [accessed on 2024-05-01].

YU, Yohgjuan. *Effects of Negative Emotions and Cognitive Characteristics on Impulse Buying During COVID-19*. Online. Frontiers in Psychology. 2022, vol. 13, no. 848256. Available at: <https://doi.org/10.3389/fpsyg.2022.848256>. [accessed on 2024-04-27].

YUAN, Rao; JIN, Shaosheng; WU, Wenchao. *Interactive effects of information and trust on consumer choices of organic food: Evidence from China*. Online. Appetite. 2024, vol. 192, no. 107115. Available at: <https://doi.org/10.1016/j.appet.2023.107115>. [accessed on 2024-05-01].

3. Legislation

Charter of Fundamental Rights of The European Union, OJ C 326/391, 26.10.2012.

Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326/47, 26.10.2012.

Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding, OJ L 25/1, 2.2.2016.

Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes, OJ L 25/30, 2.2.2016.

Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes, OJ L 091/29, 7.4.1999.

Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, OJ L 401/1, 30.12.2006.

Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae, OJ L 175/35, 4.7.1991.

Council Directive 77/94/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses, OJ L 026/55, 31.1.1977.

Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers, OJ L 192/49, 11.7.1987.

Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, OJ L 187/1, 16.7.1988.

Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, OJ L 186/27, 30.6.1989.

Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries, OJ C 179/129, 1.7.1992.

Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts, OJ L 95/29, 21.4.1993.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work, OJ L 216/12, 20.8.1994.

Council Resolution of 18 June 1992 on the marketing of breastmilk substitutes in third countries by Community-based manufacturers, OJ C 172/01, 8.7.1992.

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 011/4, 15.1.2002.

Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive'), OJ L 149/22, 11.6.2005.

Directive 2006/54/EC on the implementation of the principle of equal opportunities and equal treatment of men and women in matters of employment and occupation, OJ L 204/23, 26.7.2006.

Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on credit agreements for consumers and repealing Council Directive 87/102/EEC, OJ L 133/66, 22.5.2008.

Directive 2008/122/EC of the European Parliament and of the Council of 14 January 2009 on the protection of consumers in respect of certain aspects of timeshare, long-term holiday product, resale and exchange contracts, OJ L 33/10, 3.2.2009.

Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses, OJ L 124/21, 20.5.2009.

Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, OJ L 170/1, 30.6.2009.

Directive 2009/73/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in natural gas and repealing Directive 2003/55/EC, OJ L 211/94, 14.8.2009.

Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council, OJ L 304/64, 22.11.2011.

Directive 2014/17/EU of the European Parliament and of the Council of 4 February 2014 on credit agreements for consumers relating to residential immovable property

and amending Directives 2008/48/EC and 2013/36/EU and Regulation (EU) No 1093/2010 Text with EEA relevance, OJ L 60/34, 28.2.2014.

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127/1, 29.4.2014.

Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code (Recast)Text with EEA relevance, OJ L 321/36, 17.12.2018.

Directive (EU) 2019/944 of the European Parliament and of the Council of 5 June 2019 on common rules for the internal market for electricity and amending Directive 2012/27/EU, OJ L 158/125, 14.6.2019.

Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC, OJ L 409/1, 4.12.2020.

Directive (EU) 2024/825 of the European Parliament and of the Council of 28 February 2024 amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against unfair practices and through better information, OJ L, 6.3.2024.

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158/1, 27.5.2014.

Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181/35, 29.6.2013.

Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No 2006/2004, OJ L 345/1, 27.12.2017.

Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, OJ L 325/1, 16.12.2019.

Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC, OJ L 135/1, 23.5.2023.

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, L 404/9, 30.12.2006.

Convention on the Rights of the Child. United Nations. 1989.

European Social Charter. Council of Europe. 1965 (1996 revised version).

The International Code of Marketing of Breast-milk Substitutes. World Health Organization. 1981.

Civil Code in the version promulgated on 2 January 2002 (Federal Law Gazette . [Bundesgesetzblatt]. I page 42, 2909; 2003 I page 738), last amended by Article 1 of the Act of 10 August 2021 (Federal Law Gazette I p. 3515)

4. Case-law

Case C-120/78, *Rewe v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)*, ECLI:EU:C:1979:42.

Case C-382/87, *Buet and others v Ministère public*, ECLI:EU:C:1989:198.

Case C-89/91, *Shearson Lehman Hutton v. TVB*, ECLI:EU:C:1993:15.

Case C-233/94, *Germany v Parliament and Council*, ECLI:EU:C:1997:231.

Case C-210/96, *Gut Springenheide and Tusky v. Oberkreisdirektor des Kreises Steinfurt*, ECLI:EU:C:1998:369.

Case C-240/98, *Océano Grupo Editorial and Salvat Editores*, ECLI:EU:C:2000:346.

Case C-376/98, *Germany v European Parliament and Council*, ECLI:EU:C:2000:544.

Case C-481/99, *Heininger*, ECLI:EU:C:2001:684.

Case C-542/99, *Idealservice MN RE*, ECLI:EU:C:2001:625.

Case C-491/01, *British American Tobacco and Imperial Tobacco*, ECLI:EU:C:2002:741.

Case C-71/02 *Karner*, ECLI:EU:C:2004:181.

Case C-380/03, *Germany v Parliament and Council*, ECLI:EU:C:2006:772.

Case C-310/04, *Spain v Council*, ECLI:EU:C:2006:521.

Case C-441/04, *A-Punkt Schmuckhandel*, ECLI:EU:C:2006:141.

Case C-168/05, *Mostaza Claro*, ECLI:EU:C:2006:675.

Case C-244/06, *Dynamic Medien*, ECLI:EU:C:2008:85.

Case C-412/06, *Hamilton*, ECLI:EU:C:2008:215.

Case C-215/08, *E. Friz*, ECLI:EU:C:2010:186.

Case C-343/09, *Afton Chemical*, ECLI:EU:C:2010:419.

Case C-122/10, *Ving Sverige*, ECLI:EU:C:2011:299.

Case C-544/10, *Deutsches Weintor*, ECLI:EU:C:2012:526.

Case C-12/11, *McDonagh*, ECLI:EU:C:2013:43.

Case C-166/11, *González Alonso*, ECLI:EU:C:2012:119.

Case C-426/11, *Alemo-Herron and Others*, ECLI:EU:C:2013:521.

Case C-577/11, *DKV Belgium*, ECLI:EU:C:2013:146.

Case C-648/11, *MA and others*, ECLI:EU:C:2013:367.

Case C-265/12, *Citroën Belux*, ECLI:EU:C:2013:498.

Case C-314/12, *UPC Telekabel Wien*, ECLI:EU:C:2014:192.

Case C-269/13, *Acino v Commission*, ECLI:EU:C:2014:255.

Case C-528/13, *Léger*, ECLI:EU:C:2015:288.

Case C-157/14, *Neptune Distribution*, ECLI:EU:C:2015:823.

Case C-547/14, *Philip Morris*, ECLI:EU:C:2016:325.

Case C-133/15, *Chavez-Vilchez and others*, ECLI:EU:C:2017:354.

Case C-134/15, *Lidl*, ECLI:EU:C:2016:498.

Case C-201/15, *AGET Iraklis*, ECLI:EU:C:2016:972.

Case C-5/16, *Poland v Parliament and Council*, ECLI:EU:C:2018:483 .

Case C-147/17, *Sindicatul Familia Constanta and Others*, ECLI:EU:C:2018:926.

Case C-151/17, *Swedish Match*, ECLI:EU:C:2018:938.

Case C-335/17, *Valcheva*, ECLI:EU:C:2018:359.

Case C-380/17, *K and B*, ECLI:EU:C:2018:877.

Case C-649/17, *Amazon EU*, ECLI:EU:C:2019:576.

Case C-129/18, *SM (Child placed under Algerian kafala)*, ECLI:EU:C:2019:248.

Case C-5/19, *Overgas Mrezhi and Balgarska gazova asotsiatsia*, ECLI:EU:C:2020:343.

Case C-452/20, *Agenzia delle dogane e dei monopoli and Ministero dell'Economia e delle Finanze*, ECLI:EU:C:2022:111.

Case C-483/20, *Commissaire général aux réfugiés and aux apatrides (Unité familiale - Protection déjà accordée)*, ECLI:EU:C:2022:103.

Case C-709/20, *The Department for Communities in Northern Ireland*, ECLI:EU:C:2021:602.

Joined cases C-159/10 and 160/10, *Fuchs and Köhler*, ECLI:EU:C:2011:508.

Joined cases C-203/15 and C-698/15, *Tele2 Sverige*, ECLI:EU:C:2016:970.

Case T-171/03, *New Look v OHMI - Naulover (NLCollection)*, ECLI:EU:T:2004:293.

Case T-385/03, *Miles International v OHMI - Biker Miles (Biker Miles)*, ECLI:EU:T:2005:276.

Case T-590/10, *Thesing and Bloomberg Finance v ECB*, ECLI:EU:T:2012:635.

Joined cases T-178/03 and T-179/03, *CeWe Color v OHIM (DigiFilm)*, ECLI:EU:T:2005:303.

ECHR, *Monnat v Switzerland* of 21.09.1996 . [GC]. - 73604/01.

ECHR, *Vavříčka and Others v. the Czech Republic* of 8.4.2021 . [GC]. - 47621/13, 3867/14, 73094/14 et al.

5. Others

Alive&Thrive. *Protecting breastfeeding throughout history: The evolution of the International Code of Marketing of Breastmilk Substitutes*. International Baby Food Action Network. 2021. Available at: https://www.aliveandthrive.org/sites/default/files/timeline_document_a4_v3_0.pdf. [accessed on 2024-04-29].

Baby Milk Action. *Ireland called on to co-sponsor a Resolution on Digital Marketing*. Online. 21.3.2024. Available at: <https://www.babymilkaction.org/archives/42137>. [accessed on 2024-04-25].

Codex Alimentarius Commission Thirteenth Session. *Report Of The Eleventh Session Of The Codex Committee On Foods For Special Dietary Uses*. 1979.

Commission Notice – *Guidance on the interpretation and application of Directive 2005/29/EC of the European Parliament and of the Council concerning unfair business-to-consumer commercial practices in the internal market*. OJ 2021/C 526/01, 29.12.2021.

Communication from the Commission: *Chemicals Strategy for Sustainability Towards a Toxic-Free Environment*, COM (2020) 667 final, 14 October 2020.

Communication from the Commission: *Towards a comprehensive European Union framework on endocrine disruptors*, COM (2018) 734 final, 7 November 2018.

Communication from the Commission. *Towards an EU strategy on the Rights of the Child*, COM (2006) 367, 4.7.2006

Council. *Council conclusions on nutrition and physical activity*. OJ C 213/1, 8.7.2014.

Directorate-General for Communication. *Trade*. Online. Available at: https://european-union.europa.eu/priorities-and-actions/actions-topic/trade_en. [accessed on 2024-04-26].

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). *Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union*. Online. EFSA Journal. 2013, vol. 11, issue 10. Available at: <https://doi.org/10.2903/j.efsa.2013.3408>. [accessed on 2024-04-30].

European Commission. Executive Summary – *Consumer vulnerability across key markets in the European Union*. 2016. Available at: https://commission.europa.eu/system/files/2018-04/consumers-approved-report_en.pdf. [accessed on 2024-05-05].

European Union Agency for Fundamental Rights and Council of Europe. *Handbook on European law relating to the rights of the child*. 2022 edition. Publications Office of the European Union, 2022. Available at: https://fra.europa.eu/sites/default/files/fra_uploads/fra-coe-2022-handbook-child-rights_en.pdf . [accessed on 2024-05-05].

Government of Czech Republic. *Government favoured interests of women and children: new measures limiting harmful effects of breast-milk substitutes*. Online. 27.9.2023. Available at: <https://vlada.gov.cz/cz/ppov/rovne-prilezitosti-zen-a-muzu/aktuality/vlada-uprednostnila-zajmy-zen-a-deti-nova-opatreni-k-omezeni-skodliveho-marketingu-nahrad-materskeho-mleka-208768/#>. [accessed on 2024-04-25].

Joint FAO/Codex Alimentarius Commission Eight Session. *Report of the fifth session of the Codex Committee on Foods for Special Dietary Purposes*. 1970. 1971.

ŠAJN, Nikolina. *Vulnerable Consumers*. Online. European Parliamentary Research Centre, 2021, 9 p. Available at: [https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690619/EPRS_BRI\(2021\)690619_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/690619/EPRS_BRI(2021)690619_EN.pdf). [accessed on 2024-04-26].

TNS Opinion & Social: *Special Eurobarometer 342: Consumer Empowerment. Report*. Online. 2011, p. 7. Available at: <https://europa.eu/eurobarometer/surveys/detail/768>. [accessed on 2024-04-28].

UNICEF. *Early Childhood Development – UNICEF Vision for Every Child*. UNICEF, 2023. Available at: <https://www.unicef.org/media/145336/file/Early>. [accessed on 2024-04-26].

WHA. *WHA34/1981/REC/3 – Summary records of Committees*. Thirty-fourth World Health Assembly. 1981.

WHO. *Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual*. World Health Organization; 2017. Available at: <https://www.who.int/publications/i/item/9789241513470>. [accessed on 2024-05-05].

WHO. *Infant and young child feeding*. 2023. Available at: <https://www.who.int/news-room/fact-sheets/detail/infant-and-young-child-feeding>. [accessed on 2024-05-03].

WHO. *New WHO report: European Region is still vulnerable to predatory marketing of breast-milk substitutes*. Online 10.6.2022. Available at:

<https://www.who.int/europe/news/item/10-06-2022-new-who-report--european-region-is-still-vulnerable-to-predatory-marketing-of-breast-milk-substitutes>.

[accessed on 2024-04-25].

Protection of infant in the EU law and its proportionality with regards to EU Charter of Fundamental Rights

Abstract

This thesis examines the conformity of EU law infant protection instruments with EU Charter, both of those purposefully protecting this vulnerable group and of those having effect on more general population but influencing infants' life significantly. More intrusive clauses, that are not only of pure safety and compositional standard nature are subjected to proportionality test as developed in CJEU case-law, with regards to specificities of examined topic, notably the regulation of baby/infant/milk formulas (internationally regulated under the term of breast-milk substitutes).

Before conducting the balancing exercise, relevant legislation is analysed using interpretive methods of textual, teleological (by discussing aims of the concerned regulatory framework), historical (by focusing on context of legislation adoption) and systematic (comparing both preceding legislation and relevant related in-force legislation) interpretation. The result of analysis is also applied in specific conditions of infants involving the role of caregiver in their protection, revealing potential gaps in the legislation.

In assessment of proportionality, public health protection and children's best interest are weighted against business freedoms (freedom to conduct the business and freedom of speech). Interests of third parties – caregivers are also included, while these are neither one-sidedly protected nor interfered with by current regulatory modulation. Except of mostly positive result of proportionality test, conclusions are also drawn in regard to possible ameliorations in order to strengthen the legitimacy and effectiveness of current infant and follow-on formula advertising and labelling restrictions. Necessity

and proportionality *stricto sensu* of possible extension of the restrictions towards later age stages are also assessed, providing mixed results.

Key words:

Infant protection

EU Charter

Infant formula

Breast-milk substitute

WHO Code

Proportionality

Advertising

Ochrana kojence v právu Evropské Unie a její proporcionalita s ohledem na Listinu základních práv Evropské Unie

Abstrakt

Tato práce zkoumá soulad nástrojů ochrany kojenců v právu EU s Listinou základních práv EU, a to jak těch, které cíleně chrání tuto zranitelnou skupinu, tak těch, které působí na širší populaci, ale významně ovlivňují život kojenců. Ustanovení, která s větší intenzitou zasahují do práv jiných a která nestanoví pouze čistě bezpečnostní standardy a náležitosti složení, jsou podrobeny testu proporcionality, jak byl vyvinut v judikatuře Soudního dvora EU, s ohledem na specifika zkoumaného tématu, zejména na regulaci kojenecké/mléčné výživy (mezinárodně regulované pod termínem náhrad mateřského mléka).

Před provedením bilancování je příslušná legislativa analyzována pomocí interpretačních metod jazykového, teleologického (prodiskutováním cílů příslušného regulačního rámce), historického (zaměřením se na kontext přijímání legislativy) a systematického (srovnáním jak předchozí legislativy, tak relevantních souvisejících účinných právních aktů) výkladu. Výsledek analýzy je aplikován i na specifickou situaci kojenců zahrnující roli pečující osoby při jejich ochraně a odhaluje potenciální mezery v legislativě.

Při posuzování proporcionality jsou ochrana veřejného zdraví a nejlepší zájem dětí posuzovány s podnikatelskými svobodami (svobodou podnikání a svobodou projevu). Zahrnuty do poměrování jsou i zájmy třetích stran – pečujících osob, přičemž tyto nejsou současným nastavením regulace ani jednostranně chráněny ani rušeny. Kromě z větší části pozitivního výsledku testu proporcionality jsou vyvozovány i závěry ohledně možných zlepšení za účelem posílení legitimacy a účinnosti současných omezení reklamy a označování počáteční a pokračovací kojenecké výživy. Posuzuje se také nezbytnost a

proporcionalita *stricto sensu* možného rozšíření omezení na pozdější věková stádia, pričemž výsledky jsou smíšené.

Klíčová slova:

Ochrana kojenců

Charta EU

Kojenecká výživa

Náhrada mateřského mléka

Kodex WHO

Proporcionalita

Reklama