The EU's Distorted Dozen that endanger natural health, and UK policy actions points following Brexit

EU laws/frameworks	'The Good'	'The Bad'	'The Ugly'	How the UK can act in the interests of natural health
Food Supplements Directive (2002/46/EC, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02002L0046-20150402]	Creates a carve-out for food supplements as a category of food, rather than as medicines. Establishing high maximum amounts for vitamins and minerals that are based on good quality risk-benefit assessment will prevent arbitrary limitations of vitamin doses by national authorities (e.g. Germany, France, Denmark, Finland and Italy)	Only a limited range of vitamin and mineral forms that are on the positive list (Annex II) can be used in food supplements	The Directive has effectively prevented legal sale of many hundreds of mineral forms, including all forms of silver and vanadium. Article 5 requires that the European Commission harmonises maximum (and minimum) levels for vitamins and minerals which might, if based on poor science, restrict public access to useful/beneficial dosages	• Disband positive list approach • Do not harmonise maximum levels with any future EU levels • Take into account benefits of higher doses • Exempt foods, food supplements, cosmetics and medical devices from UK medicines law
Human Medicinal Products Directive (2001/83/EC, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02001L0083-20121116]	Legal framework for pharmaceutical drugs, as distinct from foods, food supplements, cosmetics and medical devices	The scope and definitions are so broad that any substance or combination of substances can be classified as drugs by national authorities unless they can be "clearly" characterised as foods, food supplements, cosmetics or medical devices (Recital 7)	The 'rule of doubt' cemented in European Court of Justice case law (Article 2(2)) gives national regulators a loaded gun to classify any product as medicinal - especially if there is evidence of clinical effectiveness	• Narrow the scope and definition of a medicinal product • Legally exempt foods, food supplements, cosmetics and medical devices from UK medicines law
Traditional Herbal Medicinal Products Directive 1924/2004, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2004.136.01.0085.01.ENG]	A simplified licensing scheme for herbal medicines allowing use of specific indications based on traditional use rather than very expensive clinical trials of efficacy	The scope is limited to traditional herbal medicines intended for use by the public for minor ailments and without supervision my a medical practitioner	Requires evidence of 30 years safe use including 15 years in EU. Stability requirements rule out many fully natural, multi-herb formulations. Excludes combinations with non-herbal substances. Most registered products not viewed as of sufficient	• Maintain licensing system for herbal and traditional medicinal products but make it fit-for-purpose and accessible to non-European traditions • Facilitate regime for quality herbal food supplements, even if they include one or

			efficacy by leading herbal medicine practitioners and experts	more ingredients that are also used in traditional medicines • Provide option for statutory regulation of herbal practitioners for those who want it
Nutrition and Health Claims Regulation (1924/2006, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1467791869519&uri=CELEX:02006R1924-20141213]	Prevents 'cowboy' health claims that are false, ambiguous or cannot be substantiated by any plausible science	While authorised claims on foods meeting conditions can be used EU-wide, there are pitifully few and claim wording generally not informative to consumer	Over 2,000 health claims with plausible evidence are banned and a further 1,600 affecting botanicals and related substances await a very uncertain future. Overall, the Regulation has dramatically censored the ability of business to communicate the benefits of health foods and supplements to the public	• Do not integrate key problematic parts of Regulation into any UK laws, e.g. Articles 4, 10, 13 • Dissociate altogether from EFSA's scientific substantiation requirements for 'generally accepted scientific evidence' • Develop scientifically rational scientific substantiation requirements for health claims based on scientific plausibility, existing and emerging evidence
Novel Food Regulation (2015/2283) [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R2283]	Prevents foods new to the diet of EU citizens that have been produced through technological or biotechnological means being marketed without prior safety assessment or evidence of traditional safe use in 'third	Since the cut-off date is 15 May 1997, it is becoming increasingly difficult to provide documentary evidence of prior 'significant' use in the EU as sales records are often no longer available. Accordingly many food	While the Regulation, when initially passed in 1997, was originally intended to protect EU consumers from genetically modified and other technologically altered foods, it has since become a EU protectionist tool that	• Dissociate from European Commission/EU Member State 'closed shop' approach to determining novel food status • There is a need to differentiate in law naturally-occurring and

	countries'	ingredients are incorrectly regarded as novel and are so banned as the high cost of pre-market authorisation poses an obstacle	interferes with public access to a diversity of plant, fungal (e.g. mushrroms) and algal foods (e.g. seaweeds) that have a very wide range of proven health benefits	'engineered' nanomaterials so the former are not unnecessarily forced through the authorisation process • Encourage diversification of food supply by facilitating trade in natural foods and ingredients regarded by the EU as 'novel' simply because 'significant use' within the EU either has not occurred or has not been sufficiently documented
Food Information for Consumers Regulation (1169/2011, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011R1169-20140219]	Clear labelling requirements for packaged foods including requirement to indicate provenance	Reference intakes i.e. energy 2000kcal (8,400kJ), total fat 70g, saturated fat 20g, total carbohydrate 260g, sugars 90g and protein 50g and salt 6g, may be wrongly construed by consumers as guidance amounts and ratios do not reflect best macronutrient composition for the average adult	The Regulation — and its wide scale support from government authorities and consumer groups — encourages increased rates of consumption of packaged and highly processed foods because of labelling information, so detracting from consumption of unpackaged, unprocessed or lightly processed, whole foods	• Implement re-developed non-mandatory Guideline Daily Amount (GDA) labelling for packaged foods • Develop policies and education to increase awareness of the health benefits of consuming home-prepared whole, largely unprocessed foods as part of a varied and diverse diet
General Food Law (178/2002, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02002R0178-20140630]	General rules relating to responsibilities of food business operators, including placing the onus for food safety on these operators. Contains the precautionary principle	The Regulation that established the European Food Safety Authority (EFSA) that has been, among other things, exposed for conflicts of interest, green-lighting GMOs and issuing negative opinions on scientifically valid	Misapplication of the precautionary principle, use of which the Regulation seeks to harmonise (Article 7), so that EU protectionism is maintained, either denying EU consumers free choice or presenting barriers to trade	• Dissociate from any enforced reliance on laws that results from EFSA opinions • Fair and judicious use of precautionary principle to protect consumers from genuine food-related risks

		health claim applications		• Encourage trade of ingredients and foods both within and outside the EU
GMO regulatory framework [http://ec.europa.eu/food/plant/gmo/legislation/index_en.htm], including: Directive 2001/18/EC on the deliberate release of GMOs into the environment, Regulation 1829/2003 on genetically modified food and feed, Directive 2015/412 on Member States' options for restriction or prohibition of GMO crop cultivation, Regulation 1830/2003 on traceability and labelling of GMOs, Directive 2009/41/EC on contained use of GM micro-organisms and Regulation 1946/2003 on transboundary movements of GMOs	Mandatory labelling of GMOs foods and animal feeds that has resulted in very high levels of rejection of GMO foods for human consumption in the marketplace and a consequent choice by most food manufacturers to avoid using GM ingredients or foods. 'Safeguard clause' that allows individual EU Member States to avoid cultivating GM crops even if authorised for cultivation by European Commission following positive safety assessment by EFSA	Inadequate framework for evaluating long-term environmental and human health safety and consequent authorisation of over 50 GM crops. Inadequate regulation to guard against transgene flow into non-target plants and organisms.	Insufficient requirements for scientific evidence verifying of safety of GM food and feed crops for humans and animals. Insufficient consideration given to the overall impact of GM crop technologies on human health and the environment, especially as related to combined use with glyphosate-based herbicides.	• Must prevent UK government, with its long-standing pro-GM crop stance, from relaxing already inadequate EU GM regulatory framework, and so gravely endangering human health and the environment • Based on great uncertainties around GM crop cultivation and the absence of their need to meet the food needs of humans and animals, a moratorium on outdoor cultivation should be applied (based on the precautionary principle) until sufficient case-specific data on safety are available (as per Cartagena Protocol on Biosafety)
Contaminants in Foodstuffs Regulation (1881/2006, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20160401]	Sets maximum levels of contaminants in foodstuffs so protecting consumers and improving quality standards for food and supplement industries	Inadequate range of contaminants considered. Consideration of long-term effects of consumption of specific mixtures of contaminants ignored.	Maximum levels determined more on the basis of what industry can live with rather than safety considerations. Tolerances for recognised human carcinogens such as benzopyrenes and dioxins are excessive	• The UK should develop thresholds for contaminants that are based on human health and environmental safety, taking into account the effects of mixtures and common exposures
Food Additives Regulation 1333/2008, as amended [http://eur-	Authorisation system for individual additives and food	Safety assessments required by EFSA and other	A range of additives that trigger severe adverse	• The UK should re-consider evaluations by authorities

lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R1333-20160525]	groups helps limit use of food additives for technological use	international bodies of variable quality, seemingly depending on applicant, and based on additives studied in isolation. Inadequate consideration of additive, antagonistic or synergistic effects of multiple food additives in specific foodstuffs	reactions in some people or may be carcinogenic, e.g. aspartame, benzoate preservatives, artificial colourants, are mandated	such as EFSA and the FAO/WHO's JECFA [http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/], on the basis of the latest evidence of safety and benefit, and consider the effects of interactions (e.g. benzoate preservatives and vitamin C which can produce the carcinogen benzene)
Pesticide Residues Regulation (396/2005, as amended) [http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1467795788318&uri=CELEX:02005R0396-20160212]	Provides a framework that prevents indiscriminate use of most common pesticides to providing some degree of protection of human health and the environment	Levels based on thresholds that are achievable following average use-patterns in the field, not on human safety criteria or non-target organism impacts	Many pesticides, including some that are probable human carcinogens, such as glyphosate, are mandated. The combined effects of pesticide mixtures on foods is entirely ignored	• Pesticide maximum levels should be based on safety not on levels achieved in use • Pesticide tolerances should be based on individual crop/agroecosystems so that overall pesticide inputs are minimised and development of sustainable agricultural practices are encouraged
Mutual Recognition Regulation (764/2008, as amended) [http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0764&qid=1467795861090]	A key tenet to the function of the EU single market is ensuring free movement of goods where there are no public health concerns	The impact on public health of a given product is open to wide interpretation depending on whether a given Member State wants or does not want the product in question selling in its territory	Member States like the UK have frequently not take much notice of mutual recognition, considering it a Continental European concept, only recently formerly written into EU-wide law (as opposed to being a principle of law)	• The UK must be encourage to not impose unnecessary and unjustifiable barriers to trade as it negotiates new trade deals with the EU and countries and blocs outside the EU.