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

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ments Directive (2002/46/EC,	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 • Do not harmonise m levels with any futu • Take into account be higher doses • Exempt foods, food supplements, cosme medical devices fro medicines law
icinal Products Directive , as amended)	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 a of a medicinal produ • Legally exempt food supplements, cosme medical devices fro medicines law

ticle: http://anhinternational.org/2016/07/06/eu-distorted-dozen/

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erbal Medicinal Products 4/2004, as amended)	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 efficacy by leading herbal medicine practitioners and experts	• Maintain licensing s herbal and tradition products but make i purpose and accessi European traditions • Facilitate regime for herbal food supplen if they include one o ingredients that are traditional medicine • Provide option for s regulation of herbal practitioners for tho want it
d Health Claims Regulation as amended)	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 o into any UK laws, e.g 10, 13 • Dissociate altogethe EFSA's scientific subs requirements for 'ge accepted scientific e • Develop scientificall scientific substantia requirements for he based on scientific p existing and emergi

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Regulation (2015/2283)	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 countries'	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 ingredients are incorrectly regarded as novel and are so banned as the high cost of pre-market authorisation poses an obstacle	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 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	• Dissociate from Euro Commission/EU Me 'closed shop' approa determining novel fo • There is a need to d in law naturally-occu 'engineered' nanom the former are not unnecessarily forced the authorisation pr • Encourage diversific food supply by facili in natural foods and regarded by the EU simply because 'sign within the EU either occurred or has not sufficiently documer
ation for Consumers 1169/2011, as amended)	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-devel mandatory Guidelin Amount (GDA) label packaged foods • Develop policies and to increase awarene health benefits of co home-prepared wh unprocessed foods a varied and diverse d
d Law (178/2002, as	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 health claim applications	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 reliance on laws tha from EFSA opinions • Fair and judicious us precautionary princi protect consumers f genuine food-relate • Encourage trade of i and foods both with outside the EU

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ory framework, including: 91/18/EC on the deliberate MOs into the environment, 829/2003 on genetically d and feed, Directive Member States' options for prohibition of GMO crop egulation 1830/2003 on nd labelling of GMOs, 09/41/EC on contained use of ganisms and Regulation n transboundary movements	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 go with its long-standin crop stance, from re already inadequate regulatory framewo gravely endangering health and the envi • Based on great unce around GM crop cul the absence of their meet the food need and animals, a mora outdoor cultivation applied (based on th precautionary princi sufficient case-speci safety are available Cartagena Protocol Biosafety)
s in Foodstuffs Regulation as amended)	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 deve thresholds for conta that are based on hu and environmental s taking into account of mixtures and com exposures
es Regulation 1333/2008, as	Authorisation system for individual additives and food groups helps limit use of food additives for technological use	Safety assessments required by EFSA and other 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	A range of additives that trigger severe adverse reactions in some people or may be carcinogenic, e.g. aspartame, benzoate preservatives, artificial colourants, are mandated	• The UK should re-co evaluations by auth as EFSA and the FAO JECFA [http://www.f food/food-safety-qu scientific-advice/jec the basis of the late of safety and benefi consider the effects interactions (e.g. be preservatives and vi which can produce t carcinogen benzene

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idues Regulation (396/2005,	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 should be based on on levels achieved i • Pesticide tolerances based on individual agroecosystems so t pesticide inputs are and development of agricultural practice encouraged
gnition Regulation s amended)	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 enc not impose unneces unjustifiable barrier it negotiates new tra with the EU and cou blocs outside the EU