Opinion of the European Economic and Social Committee on the 'Proposal for a Regulation of the European Parliament and of the Council on new psychoactive substances'

COM(2013) 619 final — 2013/0305 (COD),

COM(2013) 618 final — 2013/0304 (COD)

(2014/C 177/10)

Rapporteur: **David SEARS**

On 4 October 2013, the European Commission, on 7 October 2013, the Council, and on 8 October 2013, the European Parliament decided to consult the European Economic and Social Committee, under Article 304 of the Treaty on the Functioning of the European Union, on the

Proposal for a Regulation of the European Parliament and of the Council on new psychoactive substances

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The Section for Employment, Social Affairs and Citizenship, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 19 December 2013.

At its 495th plenary session, held on 21 and 22 January 2014 (meeting of 21 January 2014), the European Economic and Social Committee adopted the following opinion by 148 votes with 2 abstentions.

1. **Summary and recommendations**

1.1 The EESC agrees that the 2005 Council Decision ([1]) on new psychoactive substances (NPS) needs updating. It agrees with the need for better coordinated action between the EU agencies involved, a tighter timetable for data collection, and the possibility of a more nuanced internal classification into substances presenting low, moderate or severe risks. Any actions to restrict supply should follow these classifications in a timely and proportionate manner.

1.2 The EESC also notes that supporting data for the underpinning impact assessment were often not available, that usage of NPS varies across the EU, and that public attitudes and political responses differ sharply. The Commission is right to point out what is politically achievable within the EU treaty and the current financial constraints but should go beyond these to identify what is truly required.

1.3 The EESC believes that there are also lessons to be learned by following developments in countries outside the EU; these should be highlighted in any further impact assessments. Meanwhile improved and better resourced data collection inside the EU on all the inputs (substance availability, supply routes, economic opportunities and social need), communication routes (internet and social media) and outcomes (measurable illness and other harms) is essential.

1.4 There are a number of technical points to be clarified if the proposal for a Regulation stays as it is; these are set out in Section 5 of this Opinion. Success will depend on political support, data provision and funding from Member States. Practical objectives must be agreed. Research must continue and the best (and worst) practices for control and treatment must be identified. Plans for and outcomes from EU-funded research programmes such as eSBIRTes, Orion and ALICE-RAP should be regularly shared with others in the field and better incorporated in impact assessments and in any subsequent legislative proposals. Data collection, risk assessment and knowledge transfer should continue in real time via the Civil Society Forum on Drugs (or perhaps via a wider 'NPS Platform'), involving all stakeholders, in particular the directly involved NGOs and support groups. This should cover all NPS, including those already notified in single use, in mixtures or as adulterants in other NPS. Priorities and possibilities for action should be agreed with Member States more frequently. Alternatives or additions to a uniform EU-wide response restricted to supply-side reduction should be considered.

([1]) 2005/387/JHA, OJ L 127/32, 20.5.2005.

2. **Introduction**

2.1 A substance, whether naturally occurring or deliberately synthesised for any purpose, licit or illicit, is said to be 'psychoactive' if, in addition to its other physical, chemical, toxicological and environmental properties, it has the capacity, when consumed by humans for whatever purpose, to interact with their central nervous systems to produce stimulation or depression accompanied by hallucinations and/or alterations in their motor functions, thinking, behaviour or moods.

2.2 These effects may be regarded as helpful when the substances are formulated, prescribed and used under controlled conditions as medical products to treat specific conditions — or as unhelpful and potentially or actually dangerous, sometimes seriously so, if self-administered purely for the perceived benefits of the above effects. These risks increase sharply if the substances are also addictive and if their use is economically exploitable.

2.3 Substances such as morphine, heroin, cocaine, ecstasy and cannabis and their many derivatives and precursors, together with a range of amphetamines, barbiturates, benzodiazepines and other 'psychedelic' drugs are therefore subject to control, with varying degrees of success, under two UN Conventions [2] (1961, 1971) and a Protocol [3] (1972) implemented, to different extents, at national level around the world.

2.4 Any psychoactive substances (PS) not listed and controlled as above are described, for the purposes of EU (and some other) legislation, as being 'new' — irrespective of the time that they have been known or used for other, often legitimate, purposes. They are named as 'new psychoactive substances' (NPS) only when identified (or suspected) as being marketed or distributed solely for their psychoactive properties, for use by individual consumers acting outside of medical or other supervision.

2.5 Alcohol, tobacco and caffeine, which in various dosages fit all the above criteria for NPS and long-term harm, are specifically excluded under UN and EU definitions. This is less easy to do 'on the street' or in academic studies where their use and effects are comingled — and where the health and social impacts of alcohol and tobacco greatly exceed those of most NPS. However, researchers and regulators do not always agree on these issues and a mutually agreed process to estimate harm and risk on a quantitative basis is now urgently required.

2.6 More than 300 NPS have been identified as being (or having been) in occasional or longer term use across the EU. New notifications from Member States are currently running at around 1 per week. As they are not controlled, their use is not illicit; hence they are licit and can be described as being 'legal' — with the incorrect implication that they are also 'safe' or 'approved'. In most cases there is little scientific data to confirm or deny these assumptions. New molecules, as variants on those specifically banned, can be quickly synthesised in and imported from China or India, in some cases, in response to orders from organised groups or individuals in the EU. Existing molecules can also be diverted from legitimate purposes within the EU. In most cases, the motivation is to make money; in others, circumventing the law is the primary challenge. National Focal Points in the European Information Network on Drugs and Drug Addiction ('Reitox') provide early warnings and share information on newly identified NPS.

2.7 NPS are marketed under many non-systematic, abbreviated and/or exotic trade names, often in mixtures with other banned, new or excluded products including herbal products, medically active ingredients, food additives, tobacco, caffeine and inert fillers. There is no consistency or control over the contents; safety warnings are absent or included only to permit sales ('not for human consumption'). Labelling may be deliberately misleading ('bath salts' or 'incense' for products likely to be inhaled, smoked or injected).

2.8 Sales are by specialised dealers or commercial retail outlets ('head', 'smart' or 'smoke' shops, alongside tobacco-related 'paraphernalia') and on the internet (with credit card purchases, product and supplier reviews, and prompt home delivery all available). Anonymous web sites present special problems. Prices per dose tend to be low v. illicit drugs. Social media encourage new trends and help share experiences. Usage (as 'legal highs', club, party or recreational/designer drugs) varies sharply across the EU and appears to be growing slowly, with above average use reported in Ireland, Poland, Latvia and the UK. The number reported as being hospitalised in direct consequence remains relatively low (which, in the absence of reliable data, may or may not be a true measure of actual harm).

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[2] Single Convention on Narcotic Drugs, 1961.

[3] United Nations protocol 1972, amending the Single Convention on Narcotic Drugs.

2.9 Consistent with the above, and compared to regular, addicted, users of illicit drugs, users of NPS (in particular, in the UK, where data collection is also high) have so far tended to be young, reasonably affluent, non-criminal and more likely to present themselves for health treatment when required. Being still integrated into family and work life, recovery rates are generally good. When accidents or deaths do occur, they are usually seen as unexpected personal tragedies and tend to receive considerable attention in the media, and therefore politically, for the same reasons.

2.10 Given the above, it is hardly surprising that public and political attitudes in EU Member States and around the world to controls on NPS differ sharply. Uruguay has recently legalised cannabis. New Zealand will authorise 'acceptable' low risk and quality controlled NPS. Ireland has drastically reduced the number of retail outlets; the Netherlands and Canada are considering the same. The UK has traditionally preferred to ban products, singly or in groups but is now looking at alternative strategies. Belgium is planning to ban groups of products. Efforts have been made to restrict internet sales of illicit drugs via anonymous sites; licit sales are however likely to flourish.

3. **Summary of the Commission's proposal**

3.1 A 2005 Council Decision ([4]) set the framework for information exchange, risk assessment and control of NPS. This has proven to be reactive in use, with limited information collected, poor categorisation of risks and few options for restrictive measures. In 2011, the Council requested the Commission to update the Decision.

3.2 This proposal sets out the measures deemed necessary, including a proposal for a Directive revising the Council Framework Decision ([5]) on minimum provisions in the field of drug trafficking. This would widen the definition of 'drug' to bring NPS posing severe health, social and safety risks and subject to permanent market restriction in the EU under the same heading as substances already listed under the relevant UN Conventions and Protocol.

3.3 The proposal for a Regulation specifically on NPS is accompanied by an in-house impact assessment which highlights differences in data availability, actual use, health costs and public and governmental responses across the EU. Estimates are provided where data are not available. Policy options are assessed against their effectiveness in achieving objectives, economic, financial and social impacts, and proportionality and acceptability by stakeholders.

3.4 The proposal is based on Article 114 TFEU to ensure the proper functioning of the internal market with a high level of health, safety and consumer protection. It is intended to shorten reaction times at EU level, to provide opportunities for focused and appropriate responses, to address problems of dual use and the lack of certainty for legal operators, and to connect the market for NPS to the wider internal market.

3.5 The proposal sets out a timetable for gathering data for a joint report by the Commission, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), Europol and other European agencies closely involved (for Medicines, Chemicals and Food Safety) based on early warnings from the Member States of newly identified NPS.

3.6 This report may lead to a formal risk assessment by the EMCDDA as a basis for action by the Commission. Criteria are proposed to distinguish between low, moderate and severe health, social and safety risks. Where the risks are deemed to be low, no further action will be taken. In the case of moderate or severe risks, the Commission can impose temporary or permanent bans on the sale of specific NPS and, in particular cases, on their production, distribution, importation or exportation.

([4]) See footnote 1.

([5]) 2004/757/JHA, OJ L 335/8, 11.11.2004.

3.7 The proposal provides for re-evaluations of the levels of risk in the light of new information and for regular reporting and evaluation of the implementation, application and effectiveness of the Regulation. Research and analysis will continue. Member states will be obliged to lay down administrative sanctions necessary to enforce market restriction and to ensure that these are effective, proportionate and dissuasive. The proposal is described as having no direct impact on the EU budget.

3.8 The Regulation will come into force 20 days after publication in the Official Journal of the EU and shall be binding on Member States. The original Council Decision ([6]) will be repealed and replaced.

4. **General comments**

4.1 The EESC welcomed the 2011 Communication from the Commission entitled 'Towards a stronger European response to drugs' and the 2012 proposal for a Regulation on Drug Precursors. The EESC looked forward to proposals on 'new psychoactive substances' and suggested broad guidelines for effective action at EU and Member State level.

4.2 In the case of drug precursors, particular note was made of the extent to which the involved parties (the Commission and a limited number of legitimate manufacturers, traders and end-users) had fully embraced the requirements of Article 12 of the 1988 UN Convention ([7]) in respect of working together to achieve the desired goals. In this particular case, referring to the diversion of small quantities of acetic anhydride required for the manufacture of heroin, these could be defined quite precisely.

4.3 This is not yet the case with NPS where the situations in Member States and globally with respect to actual use and to public and political responses differ sharply. Key data are often not collected or collated; individual tragedies attract media attention; political reactions are not always supported by, and may go directly against, scientific and professional advice; other confounding factors, including the far more widespread and harmful use of alcohol and tobacco, are deemed too sensitive to incorporate within a uniform regulatory approach; a generational gap with respect to internet marketing and the role of social media in perception formation, risk taking and the recreational use of psychoactive substances, both old and new, is evident.

4.4 In this, clearly very difficult, context for anyone trying to respond on NPS, two comments from the earlier EESC opinions appear relevant, namely that *'a State's response to a threat should not cause more harm than the threat it wishes to prevent'* ([8]) and, as on many other topics of concern to regulators, *'policies should be based on data and evidence — and not the other way round* ([9])'. These may be easier to say than to achieve.

4.5 The concern with the current proposals is certainly not that they will do harm, rather that they may do insufficient good — and that their existence may delay the wider cross-societal and multi-disciplinary data-based approaches required to agree even on the current situation and on the longer term objectives for specific populations. If these cannot be agreed in advance, and any required political and financial support obtained, then this should be acknowledged in any proposal for regulation at EU level.

4.6 The EESC notes that the proposal has other aims, including addressing problems of dual use, the diversion of licit substances within the EU and the lack of certainty for 'legal operators'. However these are not quantified in the impact assessment and receive little attention in the proposal. Other possibilities to fill gaps left by other legislation have not been considered at all. It is therefore difficult to know whether the treaty base selected (Article 114 TFEU) is appropriate or not. Statistical data on the 300 substances so far listed could be used to clarify this and other points.

4.7 The EESC strongly believes, and has repeatedly stated, that regulation of supply is only one part of the solution — and by itself is unlikely to bring useful or measurable results. There must be more attention given to understanding demand — and better ways proposed to ensure that this can be met with as little risk as possible. As ever, risk can never be totally excluded — but it can be significantly diminished. Better data, properly disseminated, should help.

([6]) See footnote 1.
([7]) United Nations Convention against illicit traffic in narcotic drugs and psychotropic substance, 1988.
([8]) See EESC opinion, OJ C 229/85, 31.7.2012.
([9]) See EESC opinion, OJ C 76/54, 14.3.2013.

4.8 The EESC also notes that where criminal sanctions are applied, these must be restricted to those seeking to make commercial gain out of sales of substances already known to be banned or likely to cause serious damage to human health. This is particularly true for NPS where, so far, the risks appear to be lower than for 'old' or excluded PS and where imprisonment of users, with inevitable exposure to 'old' PS, would be the worst possible personal and societal outcome. This needs to be stated clearly in the proposal if the measures are to have credibility with the affected populations, especially the young people directly involved, in the EU.

5. **Specific comments**

5.1 The proposal provides definitions of some but not all of the key terms used — but does not explain how they should apply to this unusually structured, fast growing, part legal, part criminal, part transparent, part regulated market for products manufactured largely outside the EU. An 'economic operator' is not defined — and could presumably be licit (a seller of NPS directly, or via a 'head' shop or the internet) or illicit (a dealer in proscribed drugs). What does 'placing on the market' mean in the context of globally sourced internet sales? Why should a 'mixture' be limited to two or more NPS — rather than for instance one NPS plus varying quantities of tobacco, caffeine, herbs and fillers? Would it be better to focus on 'users' as 'anyone consuming NPS other than under medical supervision' rather than on the wider group of 'consumers' ('persons acting for purposes outside their trade, business or profession') who are largely unaffected by this activity? If the proposal is intended to be pro-active rather than reactive, should it not focus also on NPS 'that might be reasonably expected to emerge, based on scientific assessment and judgement'? Critically, why has the burden of proof shifted from suppliers, who should be required to demonstrate that their products are of 'low risk', to the EMCDDA and Commission — who could then be seen as granting approval?

5.2 The definition of NPS could also be clarified — perhaps with the 'N' standing for 'notified — under this EU proposal' — rather than 'new' only in relation to the existing UN Conventions. Given that substances are not (and cannot and should not be) routinely tested under REACH or other substance-based legislation for their psychoactive properties, there is little information on how many molecules may eventually show (or be marketed as showing) these effects to a greater or lesser degree. Given that the term 'PS' only applies when the effects are experienced by humans, the limitations of animal testing are obvious.

5.3 The EESC notes, with some concern, that the proposal focuses on individual substances rather than on the mixtures that are widely marketed. A timetable is defined for the agencies to respond — but not for the Commission to initiate either the joint report or the risk assessment. The process starts if 'several' Member States identify the same NPS; why not just one, if heavily targeted? How many is 'several'? It is unclear how the Commission will decide in the (probable) absence of further information from the agencies — and critically in the absence of political input from the Member States. There is no provision for action under other EU or Member State legislation, e.g., labelling law, sale of goods acts, general consumer protection, or other chemical, medical or food health and safety legislation. 'Head shops', if allowed to continue, should be brought fully into line with existing consumer protection law.

5.4 The EESC is particularly concerned about the lack of additional funds allocated to this work. If it can be undertaken on existing budgets, why are these procedures not followed at present? Can significant results be achieved without such funding? Is a Regulation (directed at Member States) essential for setting out how the various EU agencies interact — or can these internal processes be modified in a more timely manner by mutual consent in the light of experience?

5.5 The EESC notes that the impact assessment upon which this proposal is based is short of comparable data from all Member States on usage, impacts and health costs of NPS. If these could be shown to be general and significant, then action by the EU agencies would provide a cost-effective solution. The EESC is concerned that the proposal does not set out minimum standards for reporting — which in turn might require better recognition of and support for the largely voluntary National Focal Points who provide essential data via 'Reitox'.

5.6 The EESC agrees that NPS should be internally classified on the basis of previously agreed criteria as being, on currently available evidence of low, moderate or severe risk. However this must not be understood as granting approval for licit or safe sale and any publicly available listings should make this clear. Given the paucity of data available and the difficulties of quantitative risk assessment, reclassification based on further evidence should be expected.

5.7 The EESC also agrees with the current EMCDDA guidance notes on risk assessment of NPS that other 'old' or excluded but widely-used and better known PS should be included as markers on the same scale — including, for instance, heroin, cocaine, cannabis, ecstasy, alcohol and tobacco. If this cannot be done, given all the readily available evidence, then it cannot be done either for NPS where the evidence will be poorly available, incomplete and often contradictory; newly marketed NPS may have few social, criminal or environmental impacts but may still be severely dangerous to human health if used in this way.

5.8 The EESC believes that this more holistic approach to addiction and drug dependency would also lead to better funded preventative approaches and remedial treatments at national level. Understanding the practices and attitudes of different age groups (10-18, 18-25 and 25+) will be essential. The role of social media and online marketing and advice services in forming trends or sharing warnings are already important and will increasingly dominate personal decision making in this area. Projects monitoring this must be encouraged and fully funded. The proper protection of health should take priority over justice and the internal market.

5.9 The EESC recognises that in due course regulation may be required; however the need and shape of this legislation is far from clear. Member States perceive different problems, prefer different solutions and must be allowed to take action on different timescales. Around the world there are stark contrasts between restriction and authorisation. It will be helpful to follow developments in two adjacent, economically and culturally-similar countries in the Southern Hemisphere, Australia and New Zealand. Close cooperation with the USA and other countries providing internet supplies will be essential. Trade talks with China and India should include measures to limit the manufacture and sale of old, excluded and new PS.

5.10 This is above all a truly global problem — and any further impact assessment and proposal for regulation should include these dimensions and consider a wider range of options, even if these are initially seen as being difficult to implement at EU level. The EMCDDA will play a key role in this. If further funding is required it should be provided. Relevant research programmes should be more closely coordinated and their results more widely shared. When legislation, at whatever level, is required it will hopefully have a stronger base of evidence to resolve the questions raised above.

Brussels, 21 January 2014.

The President
of the European Economic and Social Committee
Henri MALOSSE