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Title: Assessing the 'added value' of European policy on new psychoactive substances.

Abstract:

New Psychoactive Substances (NPS) are reported to be on the rise throughout Europe, and are often

presented as the latest challenge facing drug-policy makers. At the European level, legislation on

NPS has existed since 1998. Several evaluations, however, have suggested that this legislation is not

effective and the European Commission has submitted a new proposal on NPS seeking to extend its

powers in this area. This article critically evaluates the new proposal against its predecessor's three

main criticisms: (i) being unable to tackle the large number of NPS because of lengthy European

legislative approaches, (ii) being reactive rather than proactive, and (iii) lacking options for regulatory

and control measures. In determining whether or not European interventions can bring added value to

what is being done at the national level, it finds that, while the new proposal is more efficient, it is not

necessarily more effective, and that there is a disappointing focus on legal frameworks at the expense

of research and harm reduction.

Keywords:

Drug policy; European harmonisation; new psychoactive substances; harm reduction; evidence based

policy

Introduction:

The latest phenomenon to catch the attention of drug policy makers and practitioners around the globe

has been the rise in the popularity, availability and use of New Psychoactive Substances (NPS) - a

catch all term for chemical compounds that have been modified and developed to mimic the effects of

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drugs that are already prohibited. Some NPS have already been regulated in many countries (e.g. mephedrone, synthetic cannabinoid agonists), but, given the ease of slightly tweaking chemical structures to create new substances, many remain outside the confines of national and international regulations. This is not a new problem *per* se, but the last decade has seen an increase in their "range, potency, profile and availability" (Winstock & Ramsey, 2010, p. 1685). Existing national and international illicit drug legislation has been generally reactive in its response to controlled drugs; a new substance is developed, marketed, gains in popularity, comes to the attention of the authorities and, where warranted, is eventually added to the list of controlled substances. NPS, however, may present a new kind of drug market where substances are emerging and evolving rapidly, within which new provisions are needed to keep pace with the capacities of developers to create new substances.

Latest figures from the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) indicate that more than 450 potentially harmful new psychoactive substances (NPS) are now being monitored in Europe (EMCDDA, 2015a), and the European commission has claimed that NPS "are emerging at an unprecedented rate" (European Commission, 2011a). On a global scale, the International Narcotics Control Board (INCB) has declared that this situation is causing "increasing concern" (INCB, 2011, p. 97) and the United Nations Office on Drugs and Crime (UNODC) has recently developed its own early warning advisory (EWA) to share information on NPS on a global scale. There is clear evidence that the issue of NPS is one that is being prioritised, yet, while most regions in the world confirm the appearance of NPS within their internal drug markets (UNODC, 2013), the limited information that is available on prevalence rates suggests that they remain relatively low, with about 8% of the youth population reporting use across Europe (EMCDDA, 2015a.

Furthermore, various academics have questioned the dominant discourse in this area. For example, Reuter (2011, p.4) has described the problem as "modest and localised" with

"no major disasters (large numbers of deaths or serious injuries/infections on the one hand; large and violent illegal markets on the other) associated with new substances in recent years" (Reuter, 2011, p. 27).

Birdwell, Chapman & Singleton (2011), further elaborate that it is unusual for an NPS to cause widespread and significant problems (e.g. mephedrone in the UK and BZP in New Zealand) and van Amsterdam, Nutt & van den Brink (2013, p.317) confirm that 98% of NPS are little more than "one-night wonders".

Nevertheless, NPS have become a driver for changing drug policy landscapes. Traditionally, drug legislation lists individual substances which are to be controlled, but systems have also been developed which allow chemical compounds that are structurally similar (generic model) or which are perceived to have similar effects (analogue model) to existing controlled substances to be automatically controlled at any one time. These alternative systems can be useful in responding more proactively to the development of NPS and have been employed in many individual countries. Other countries have also responded to NPS by introducing emergency legislation that allows a substance to be immediately banned for a specific time period without undertaking the lengthy and time consuming legislative procedures necessary to bring a substance under permanent control. Finally, a handful of countries have established a system whereby any substance meeting certain criteria (e.g. psychoactivity) will be subjected to a total ban. This system has been adopted in Ireland, Poland and Romania, and the UK. (EMCDDA, 2015b).

There has also been some experimentation with regulation via the frameworks that govern foodstuffs, medicines and specific commodities such as alcohol and tobacco (Reuter, 2011). Medicines laws have been utilised in at least 8 European countries and different types of consumer safety laws have been employed in Italy, Poland, Portugal and the UK (EMCDDA, 2012), although efforts have been somewhat sidestepped by the marketers of NPS declaring them 'not for human consumption'. The

most radical example of alternative regulation, however, was proposed in 2013 under New Zealand's Psychoactive Substances Act. This legislation aimed to shift the burden of responsibility for determining the potential harms of an NPS to the vendor: if substances passed the extensive and expensive tests (funded by the vendors and expected to cost between 1-2 million NZ\$) and were deemed to be of low risk of harm, then they would have been licensed for sale in restricted outlets and subjected to constrictions on age of purchase, promotion, and advertising. The Act, however, hit a stumbling block when a government amendment cut off the licensing phase and halted the legal sale of all psychoactive substances making the likelihood of future approvals much more remote (Brown, 2015). The amendment also prohibited the use of animal testing in determining the safety of a product leading Brown (2015, p.1) to suggest that an impasse has been reached as the legislation passing through the New Zealand parliament "cannot possibly approve or license any product".

While national responses to NPS vary considerably, responding to this challenge has been identified as a priority at the European level. Europe has been at the forefront of NPS policy development since a 1997 Joint Action (European Council, 1997) on the control of new synthetic drugs established a mechanism for information exchange, risk assessment and control, which was later solidified in a 2005 Framework Decision (Council of the European Union, 2005). In 2011, the European Commission communicated its desire to produce stronger EU level regulations in this area (European Commission, 2011a), and in 2013 new proposals for a regulation and directive on the treatment of NPS in Europe were presented (European Commission, 2013). In April 2014, the European Parliament indicated its strong support for these proposals, but discussions among member states were stalled over the correct legal basis for the proposals. In April 2016, these discussions were resolved and the proposals were once again put forward on August 29th with a slightly amended legal basis. It is the aim of this article to consider whether legislative responses at the EU level provide added value over national responses, particularly considering the diverse cultural context of NPS use and the differences in legislative responses thus far.

Existing European Policy on NPS

The control of NPS is an area of drug policy making where the EU is already relatively active. Within the EU, drug policy is an issue where the principle of subsidiarity has been applied, leaving decision making power in the hands of national governments. The EU itself can only intervene where it can be demonstrated that European intervention brings added value that national governments cannot achieve alone. This has meant that national drug policies within Europe tend to vary considerably, from countries such as Sweden where a zero-tolerance approach is taken, to countries such as the Netherlands or Portugal where the principles of normalisation and harm reduction are more rigorously applied (Chatwin, 2003).

Nevertheless, commonsense dictates that drugs are an international issue: it therefore makes sense for national governments to work together, particularly in relation to law enforcement agencies such as the police and prosecution services. To date, the most advanced European level policy making in the field of drugs lies in the creation of two Framework decisions: the first, passed in 2004, sets out minimum-maximum penalties (the lowest maximum penalties allowed) for drug traffickers (European Commission, 2004) and the second, passed in 2005, deals with the control of NPS (European Commission, 2005). The 2005 Framework Decision on NPS has three main functions (EMCDDA, 2007). Firstly, it establishes a mechanism to facilitate the rapid exchange of information between European and neighbouring countries on the NPS appearing within their internal markets. Secondly, it outlines the process for conducting an assessment of the risks associated with individual NPS. Thirdly, it stipulates the protocol for bringing a substance under control if the Council decides that it presents an unacceptable risk. If it is subjected to control measures then member states have 12 months to bring this into effect within their own borders.

Since the implementation of this Framework Decision in 2005, bans have been slow, but steadily increasing: BZP was banned in 2008, mephedrone in 2010, 5-IT and 4-MA in 2013, 4 more in 2014, and 7 in 2015. This relatively low number is somewhat surprising given the high number of substances now being monitored in Europe and has contributed to the perceived need for several evaluations of the 2005 Framework Decision (Chatwin, 2013; European Commission, 2011b; House of Lords, 2011; RAND, 2012). Results suggest that the creation of an 'early warning system' which collects and disseminates information on NPS from across member states, has been welcomed (House of Lords, 2011) as the first of its kind in the world. Criticism, however, surrounds the ability of the risk assessment and control procedure to effectively control the NPS market. In 2011, the European Commission deemed the Framework Decision to be "inadequate" (European Commission, 2011a, p. 7) and outlined its main failings as (i) being unable to tackle the large number of NPS because of lengthy European legislative approaches, (ii) being reactive rather than proactive, and (iii) lacking options for regulatory and control measures (European Commission, 2011a).

The new EU proposal on NPS

The first steps towards strengthening EU policy in this area have been taken with the release in 2013 of a new EU proposal on the regulation of NPS within its borders (European Commission, 2013). Increased European action is officially justified on the basis that: "Member States alone cannot reduce the problems caused by the spread in the internal market of harmful new psychoactive substances" (European Commission, 2013, p7). The new proposal aims to improve existing legislation in a number of ways. Perhaps most significantly, it seeks to speed up existing processes by introducing an immediate temporary ban on substances "suspected to pose immediate public health risk" (European Commission, 2013, p. 4) and to introduce a response which is "proportionate to the health, social and safety risks" (European Commission, 2013, p. 13) posed. Under this proportionate system, a risk assessment will be conducted by the EMCDDA scientific committee and the Commission will determine whether the risk posed is of a high, moderate or low nature. Substances posing a high risk

will be brought under permanent EU wide legislative control, those posing a moderate risk will be subjected to consumer market restriction and will be unable to be sold to the public except for in authorised cases such as legitimate medical use, and those posing a low risk will remain unrestricted. In addition to these changes, the proposal contains pledges to increase the research that is done on substances, both before and after they are categorised, and to remove obstacles to the continued legitimate use (e.g. for medical, scientific or industrial purposes) of substances after they have been restricted.

Evaluating the 2013 European proposal on new psychoactive substances

The following evaluation of the new proposals is based whether it can effectively address the three main critiques of existing legislation.

Existing legislation is unable to tackle the large increase in the number of new psychoactive substances due to lengthy European legislative processes

The new EU proposal on NPS entails a significant extension of powers, allowing the European Commission to immediately ban a substance that is suspected to have the potential to cause significant harm to users. This is a power that many individual countries have already adopted because: "drug use can spread very quickly and once a drug market has passed a tipping point effective regulation usually becomes more difficult" (Coulson & Caulkins, 2011, p.768). Introducing the ability to implement a 12 month immediate ban on a substance will certainly allow a more rapid curtailment of the market, and it could thus be argued that this measure will facilitate a more effective European response to NPS. Increasing the speed with which the potential harm of NPS can be decided upon, however, is not without problems of its own: namely that the possibilities of building an evidence based policy will suffer a significant setback.

The risk assessments of substances such as BZP and mephedrone, consistently report a lack of scientific evidence about the effects and potential harms of the substance (EMCDDA, 2011b). These risk assessments have taken at least a 12 month period to conduct, so the ability for immediate decisions to be grounded in evidence is therefore questionable. Furthermore, the new proposal states that an immediate ban would be implemented based on both prevalence rates and patterns of use, and "on fatalities and severe health consequences" (European Commission, 2013, p. 22). This issue of fatalities and severe health consequences, however, remains a particularly problematic basis on which to decide the level of harm. A report on mephedrone (EMCDDA & Europol, 2010, p. 14) raises the important point that, while numerous fatalities related to mephedrone have been relayed in the popular press, in countries such as the UK and Romania for example, the role that mephedrone played in the deaths remains unconfirmed and that, to date, "there has only been one confirmed death related solely to mephedrone".

While scientists recognise the desire for speed in relation to NPS, they also caution against making snap judgements that may impede the ability to conduct more research, especially on potential health risks, once a ban has been implemented. Reuter (2012), in particular, encourages us to value the lengthy processes that are entailed in making legislative decisions about NPS as we can be more assured that those decisions are underpinned by scientific evidence and expert consideration.

The need to sacrifice the process of gathering scientific evidence in order to respond swiftly to an emerging NPS contributes to what Stevens & Measham (2014) have termed the 'policy ratchet': responding quickly to an NPS which is perceived to pose a threat becomes all important and, in the absence of scientific evidence, the tendency is to progressively increase sanctions and to classify NPS as illegal drugs on "precautionary grounds" (Hughes & Winstock, 2011, p.1895). Stevens & Measham (2014, p.1226) have applied the phrase "guilt by molecular association" to describe the situation where bans are being implemented, not because of any proven harm of the

substance itself, but because of a presumption of harm based on similarities with other prohibited substances. Reuter (2011, p. 22) neatly summarises the situation here:

"The adverse consequences of mistakenly refraining from prohibiting what may turn out to be a dangerous drug are massive both for the individual decision maker and for the political party in power at the time. On the other hand the gains from correctly allowing a new psychoactive substance to enter the market, with appropriate regulatory controls, are modest and not very salient for the decision maker or the government".

In terms specifically of the temporary one year ban proposed by the EU, Birdwell et al. (2011) suggest that once an NPS has been subjected to this measure it is extremely likely to become permanently controlled because, in the event of a u-turn, it would be very difficult to revisit convictions imposed while the ban was in force and because a reversal could well be seen as an endorsement of the safety of the substance. The details of the proposal itself further contribute to the problem of the policy ratchet: while provision has been made to ensure that member states are free to impose national regulations in relation to substances that have not been acted upon by the EU, there is no such assurance that they may opt out in cases where the EU has decided to impose European level regulations (European Commission, 2013). Therefore, while the new proposal does speed up the legislative process, the value of this, particularly in terms of building evidence based policy, remains questionable.

Existing legislation is reactive rather than proactive

The European Commission's own evaluation of the functioning of the 2005 framework decision (European Commission, 2011b) on NPS was fairly comprehensive about the need for encouraging and supporting increased research in this field in an effort to create a more proactive policy. The evaluation specifically called for

"a clear mandate to purchase new psychoactive substances and analyse them; to purchase and synthesise reference samples; to disseminate analytical information to Member States and to carry out toxicological and epidemiological studies" (European Commission, 2011b, p15).

The EU is, generally speaking, well accomplished in stimulating, collecting and disseminating information on illicit drugs and has supported efforts to build an evidence based drug policy (EMCDDA, 2010). Given this background, the new proposal is relatively light in its provisions for research. It does make the commitment to provide wrap around monitoring of NPS. Beyond this, however, it neither commits to significantly improving forensic data, nor turns the focus to increasing our knowledge about neglected areas such as prevalence, treatment, prevention strategies, or user experiences and motivations.

One area in which the new proposal is more forward thinking in terms of research is in its commitment to remove the barriers to trade in NPS for legitimate purposes. This is largely achieved by allowing those substances which pose only a moderate risk to be subject to consumer regulations which prevent trade *except* for legitimate purposes and by mandating that those presenting severe risks will still be authorised for specific industrial or commercial purposes, as well as scientific research and development. Academic scholars have also focused on this issue, suggesting that the blanket banning of NPS has had a detrimental effect on research into NPS and their potential legitimate and medicinal uses (Nutt, King & Nichols, 2013).

Existing legislation lacks options for regulatory and control measures

The new proposal also entails an attempt to introduce a system of response that is proportionate to the degree of harm posed by an individual substance, thus achieving a more diverse range of options for regulatory and control measures, including the possibility that a substance could be deemed of low

enough harm to remain uncontrolled. Laying aside this interesting but under-developed final point, which has played a contributory factor in some Member States challenging the proposal, the fundamental problem here is that it is by no means certain that bringing substances under control has any significant effect on their market, and, in contrast, many have suggested that it may in fact *increase* overall harm (van Hout & Brennan, 2011; McElrath & O'Neill, 2011; Measham, Moore, Newcombe & Welch, 2010; Perrone, Hegelson & Fischer, 2013;). For example, Wood, Measham & Dargan (2012, p. 95) studied mephedrone use amongst gay clubbers in the UK *after* it had been banned and found that use "may be increasing" and Birdwell et al. (2011, p. 19) found that once the ban had been implemented "other seemingly more dangerous substances emerged, including NRG-1, Ivory Wave and Benzo Fury". Furthermore, the EMCDDA (2011a, p. 3) reports that "control of GHB ... may have led to a rise in the use of its chemical and metabolic precursor GBL..., which is at least as dangerous as GHB". Others have reported that stricter control can also result in a decrease in purity of substances available (Miserez, Ayrton & Ramsey, 2014) and an increase in price (Wood et al, 2012).

Given the uncertainty surrounding the effectiveness and overall benefit of policy interventions that bring substances under control, Rolles (2009) suggests that those responsible for implementing them ought to seek not only to research the potential harms of a substance but also the potential harms of the polices that are put in place to control them. In turn, van Amsterdam et al. (2013, p.323) suggest that policy makers

"should subscribe to and focus on a more holistic approach, where harm reduction is the guiding principle ... citizens cannot be stopped from using drugs through more restrictive legislation and the general aim should be to minimise the harm of (any) drug use as effectively and efficiently as possible".

Yet, the new EU proposal does not provide much in the way of harm reduction. Member states will be free to decide whether or not to criminalise the users of an NPS once it has been brought under

control (either permanent or temporary), but there is nothing to promote education or prevention methods and nothing to suggest that implementing control measures may bring adverse consequences to users. This is particularly interesting as the EU has a relatively strong track record on the provision of harm reduction within its drug policies. It is now a requirement of entry to the EU that prospective member states offer minimum harm reduction measures such as needle exchange programmes and substitution treatment programmes (Chatwin, 2013), and Rhodes & Hedrich (2010) document an increased focus on harm reduction in the detailed objectives of the most recent drug action plan (Council of the European Union, 2013).

Discussion

The new EU proposal evaluated above clearly does bring some benefits. For example, under this proposal, the EU could react immediately to NPS that pose a serious threat. They will have a graduated range of responses available once a risk assessment has been conducted, which include the possibility of deeming a substance to be considered of a low enough risk to be allowed to enter the legitimate market, and have sought to protect trade in potentially harmful products for legitimate uses. They will certainly be able to claim that they can react more quickly to emerging NPS and that they have sought to provide a greater range of control options. In sum, the changes analysed above represent a significant increase in capability and speed of legislative and regulatory response, and a significant extension of powers at the European level. The intention to "scale up" (European Commission, 2011a, p. 10) its response to NPS in this way was announced by the European Commission in 2011 who cited "new opportunities provided by the Lisbon treaty" (European Commission, 2011a, p. 10) as the factor underpinning these changes.

Under the Lisbon Treaty, drugs are defined as one of the "particularly serious crimes with a cross-border dimension" (Official Journal, 2007, p. 4) and the passing of this treaty thus allows for the easier establishment of minimum rules and sanctions in this area. Legislation can now be established

by directive rather than framework decision and relies on Qualified Majority Voting (QMV) rather than unanimity (House of Lords, 2012). This does remove some of the bureaucratic hurdles to passing legislation on drugs, including NPS, but does not remove the application of the principle of subsidiarity – the EU must still prove that their interventions bring 'added value' to national policies. Furthermore, these proposals can be conceptualised as an attempt to *force* harmonisation of policy in member states via top-down methods of control that can be termed hard harmonisation (Bennett, 1991). Standring (2012, p.12), however, suggests that applying the principle of subsidiarity to an area "is a tacit admission that hard, legislative integration processes are not the most appropriate tools", and instead advocates more subtle methods of 'soft convergence' whereby similarity of policy is *encouraged* through the application of common guidelines, the sharing of instances of best practice, and the bringing together of networks of a variety of actors with interests in the area.

Standring's (2012) position has much in common with more generally applied theories of European integration. Garcia (2006, p.745) contends that the application of subsidiarity within the EU has contributed to a shift from government to governance which "seeks the involvement of stake holders and civil society organisations besides government bodies and experts". Piattoni (2010, p.255) has suggested that multi-level governance (Marks, 1992), combining supra-state, national, and local or regional levels of control, now provides "the best single description and explanation of how the EU actually functions". Others (Stephenson, 2013) have argued that policy making within the EU is now too complicated to be contained within the three layers of multi-level governance and have sought to apply theories of network governance (Rhodes, 1996) whereby states and supra-state institutions are conceptualised as the activators of networks rather than the formulators of policy (Eising & Kohler-Koch, 1999).

Seddon (2014) has recently applied similar ideas to the specific area of the control of NPS. Drawing on the existing body of work on regulatory theory, he suggests that we need to apply a "fundamental

rethinking of the contents of the drug policy toolbox" (Seddon, 2014, p.12) that favours attempts to harness the cooperation of multiple actors (networked governance) in the regulation of NPS over hierarchical attempts to regulate that are heavily dependent on law enforcement and criminal sanctions. Given these theoretical developments in our conceptualisation of European integration, and Seddon's (2014) application of them specifically to the phenomenon of NPS, the European proposals can be critiqued for their focus on hierarchical and law enforcement orientated methods of regulation. Drawing on the discussion above, the European proposals could therefore be viewed as both one-dimensional in their approach to regulation and out of touch with current conceptualisations of 'best practice' in European integration theory.

The EU has argued the case for the 'added value' of this type of regulation by suggesting that divergent national responses may be detrimental to solving the problem of NPS. This is fairly typical of the line taken by the EU in relation to drug policy in general – the differences in rules and cultural practices at the national level contribute to the difficulty in the ultimate control of illegal drugs. It assumes two things: firstly, that all member states are experiencing the same problem and secondly, that it therefore makes sense for member states to work together and implement the same responses. Neither of these factors, however, have been clearly evidenced. Information on NPS prevalence levels is patchy at best and generally reports low levels of use: the EMCDDA (2012) suggests that use is much higher in some countries than others. Furthermore, the nature of the problem differs with GHB raising particular concern in the Netherlands, mephedrone in the UK, PDU in Hungary and synthetic cannabinoids in Germany.

Taking this information into account, there may not be any 'added value' in forcing all member states to act uniformly on emerging NPS, and, in some cases, such an act may even bring harm of its own.

If several member states have not experienced a problem with an individual NPS, implementing a national ban may be a time consuming and costly bureaucratic process without much reward. More

seriously, some research tentatively suggests that the parliamentary discussions that go alongside banning a substance, together with the media attention that is focused on that substance, can result in rising numbers of young people reporting use (Davies, English, Stewart, Edgington, McVeigh & Bellis, 2012; EMCDDA, 2011b; Shapiro, 2011). Furthermore, as outlined above, the small number of research studies that have been based on the experiences and motivations of users have found many unintended and negative consequences of control oriented policy responses to NPS.

A wider appraisal of EU drug policy in general (see Chatwin, 2013; Chatwin, 2011), however, suggests that the EU does have the potential to bring 'added value' to developing NPS policy in areas that lie outside the scope of law enforcement and which do not follow traditional top-down methods of government. For example, as discussed above, the EU has a strong track record in the application of the principle of reduction of harm to the users of substances and the promotion of an evidence based policy, neither of which feature significantly in the new proposals. Furthermore, in direct opposition to the claim that policy on NPS is harmed by the diversity of response at the national level, and that we must all work together and do the same thing, Hughes and Winstock (2011, p. 1898) suggest that the emergence of NPS provides "the opportunity to try novel policy and legislative responses": the very diversity of response seen across Europe might thus bring value in the search for effective and evidence based policy responses with which to kit out Seddon's (2014) toolbox. European level institutions are therefore ideally placed to bring 'added value' by putting in place the infrastructure to ensure that a variety of actors are brought together to think creatively about the regulation of NPS, and to share evaluations of implementations and incidences of best practice.

Conclusion

There is little doubt that the new proposal would bring increased and more diverse regulatory powers at the European level, and allow for a faster response to emerging NPS. There is limited evidence, however, that this top-down, hard harmonisation oriented response will bring added value to policy that exists at the national level. Instead of continuing to focus solely on law enforcement options, the EU could also commit valuable resources to the development of initiatives to reduce the added harm done to the users of NPS, and instead of promoting speed at all costs they could prioritise the gathering of evidence and the exchange of information. In line with current theories of European integration in general, at this stage in the emergence of the NPS phenomenon, it may actually bring more value to allow a diversity of response to NPS that is contributed to by a wide range of actors, and underpinned by evaluation and the sharing of instances of best practice. Finally, at a time when the world is carefully evaluating more than 40 years of a war on drugs policy, it seems somewhat incongruous for European proposals to focus so exclusively on developing and strengthening law enforcement responses at the expense of a response that encompasses harm reduction, education and prevention.

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