# PAS 8855:2023 Comments

## 4.1.2 – This is a ban on a number of ingredients proposed in the PAS

Exclusion of all respiratory sensitisers is not necessary, many ingredients are minor respiratory sensitisers. The STOT-RE Category 1 exclusion is there for this purpose, having this broader ban would have a detrimental effect on companies developing gourmet flavours for open tank systems.

Sweeteners, appear to be included for social purposes rather than as an identified scientific hazard, compounds should be banned because of their physical/chemical properties not because of their function. – this is a step towards a flavour ban

Preservatives, as above a class of compound should not be banned, all individual chemicals should be banned based on their physical and chemical properties, these properties should be debated and added to an exclusion list.

## 4.1.4 A new Quality Control requirement that will be challenging for disposables and pods

Weight and volume cant be easily assessed in disposable products, there is no agreed standard for making this measurement, before and after fill weights can be misleading due to variability in product weight from manufacture, and efforts to measure the volume of liquid by various means are not reliable- so this should not be included until there is an agreed method for making such measurements.

## 4.1.5 – A requirement for shelf life studies for all products.

This is a new requirement on top of the legislation, and whilst good practice its an additional cost for smaller manufacturers to bare when developing new products.

## 4.1.6 – Child-resistant packaging needs certifying for devices/disposables

Requiring certified child resistance packaging is fine for 10ml bottles, however it’s not a current regulatory requirement for it to be certified, and requiring it will be detrimental to smaller manufacturers of pods and disposable systems, which have non-standard packaging and off-the-shelf child-resistant packaging is not available, they will need to get their own packaging tested and certified. This is a considerable expense

## 4.2.1 – Full traceability for all products

Full traceability is expensive to implement and has only just become a requirement in the tobacco industry at huge expense, this requirement will favour those tobacco companies that have these existing systems and be a significant determent to smaller companies that will need to develop them or buy them in. the benefits of these systems are of limited value to these businesses.

## 4.3 A requirement to hold a full technical dossier for each product being sold

Whilst this is good practice it’s not a current requirement and will place a significant burden on manufacturers with large product portfolios, this should be simplified to a signal technical dossier that covers all products of the same class, so a single one for 10ml products and a single one for a range of disposables or similar devices.

## 4.4.1 Maximum emissions being set for all products that are the same, low-powered disposables and open tank systems are set for the same target

Setting levels of degradants and metals is something that the industry and regulators have struggled with for some time. It is closely linked to the level of risk you are happy to accept for a combustible alternative. This is a point of public health policy and should not be set by a standards committee

Also, lower powered devices such as pod systems favoured by tobacco companies will find these standards easier to pass than smaller manufacturers that sell open tank systems etc.

I feel this could effectively ban the open system products,

## 4.4.2 Requires all systems to be tested at their maximum settings and extend the testing from a single test to a full lifecycle test

The requirement to test all systems at their highest levels combined with the above thresholds will effectively ban open systems and thus to some extent 10ml bottles.

These devices have a range of power settings including some which may be beyond what most consumers would use, by requiring testing at these extremes would make it extremely hard for these devices to pass the standard.

Also, the need to do emissions testing through the full lifecycle of the product is a massive increase in testing burden and would raise the cost of TPD testing exponentially, this will be a massive determent to smaller manufacturers.

## 4.5.4 – Full traceability required for all products

Whilst this is good practice it is regulatory creep and will be burdensome on smaller manufacturers.

## 4.6 – A fully digital customer complaints database will be required

Forcing companies to maintain a digital complaints system when they receive so few complaints is burdensome, whilst having a protocol and system is good practice forcing digital systems on smaller manufacturers will be an additional cost burden.

## Annex A toxicological risk assessment

## A1 – all ingredients will be subject to a thermal stability test

Requiring thermal stability studies on all ingredients is regulatory creep and extremely burdensome on industry.

## A2 – All vapour needs to be fully tested to identify breakdown products and then a toxicology assessment of those components undertaken

This level of assessment is extremely expensive to identify all by-products from use and is regulatory creep and burdensome on industry.

## A3.1 – If limited tox data is available it must be derived in-silico

This requirement to develop toxicological data where the literature does not provide it using QSAR is an expensive and expert process and access to the skills needed is limited – this is well beyond the current requirement to compile existing data and is burdensome on industry.

## A.3.3 – Increases the qualifications required to complete a toxicology assessment on a vape product

The requirement for a toxicological risk assessment to be done by a trained and registered toxicologist is regulatory creep, at most it should be somebody with a relevant qualification such as a degree in pharmacy as with current cosmetic regulations, access to registered toxicologists will drive significant cost for each product being assessed and will be burdensome on industry.

The accountability of the TRA on the toxicologist will mean the toxicologist will need insurance which again will drive costs.

## A.3.4 All products need to undergo a battery of testing in the laboratory to confirm safety

This whole section is regulatory creep, and has limited value in that these products are generally of low risk and each ingredient will be assessed via the literature. This is an extremely expensive testing and new regulation that will prevent many companies from being able to afford to develop new products.