Enforcement of in-situ generated Biocides: an example : Ozone Generation

Mike Prince, Chairman EuOTA

Overview

- Background: difference between conventional liquid chemicals and in-situ generated
- Explanation of devices and the Biocidal product
- Market background for ozone generation in-situ biocides
- What does the law say…how will it be interpreted
- The key issues
- Proposed structure for enforcement and how to work together

Conventional liquid biocides compared to in-situ generation

- Conventional Liquid Biocides are no longer produced when not approved. Manufacture stops
- Period of phase out allows stocks to be run down so the product is removed from the market
- In-situ generated devices rely on components which in themselves are not illegal so therefore available….. so in theory devices could last forever.

Devices on the market

Management and control of devices is the key

- Numbers…….hundreds of thousands if not millions of devices on the market
- OEM's……many integrated into other devices.
- Not all devices are obvious as different descriptions : activated oxygen, ozone, triatomic oxygen

Devices scale

A washroom device

- 0.05g/h

A potable water plant

- 2000g/h

The output of ozone generating devices can be from 1 mg O3/hr to 20kg O3/ hr
The size of device can be 1 cm3 to 6m3

Devices
OEMs

- fridge

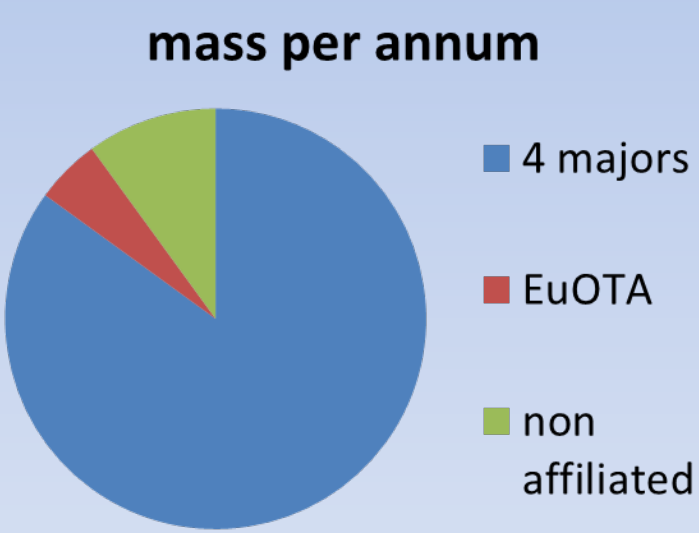
- spas

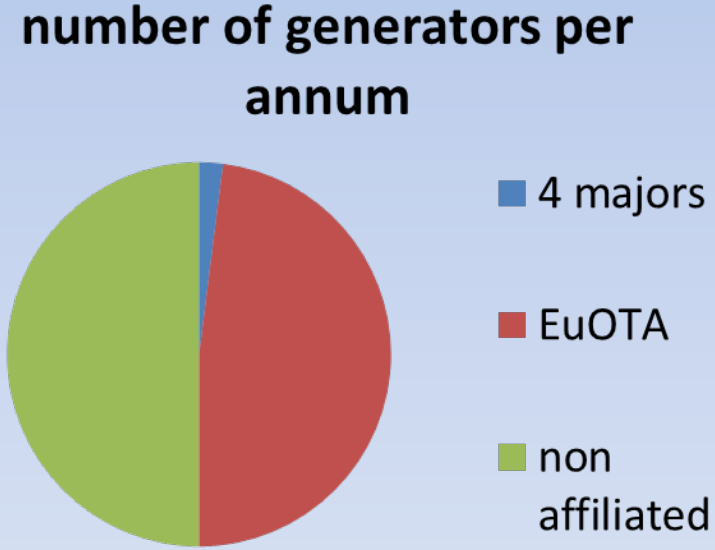
What if the device is built into a product and cannot practicably be removed?

Market background : Ozone

- Two ozone consortia : EuOTA and Euro3zon
- Currently c 45 companies seeking compliance
- Market total of >200 ‘manufacturers’ identified as supplying the EU market.
- Two consortia have completely different membership bases
- Euro3zon (8 members) Euota (c120 members)
- All Euro3zon members are seeking compliance
- 37 EuOTA members seeking compliance
- Circa 100 manufacturers not involved in anyway with either consortium

Estimated European ozone market size (representative figures)





Current status of the BPR : ozone

- All products protected under article 93 provided they fall within PT's 2,4,5 or 11
- All other applications are illegal today
- Once the ozone dossier(s) is approved 18 months given to submit product applications
- At product application submission all products not submitted….should be 'removed from the market'
- Products submitted for approval can remain on the market until authorisation decision is made. If not approved then are removed from the market.
- Any new product has to go through the complete approval process before it can be supplied
- The product application deadline for ozone is currently expected to be in 2023 / 24.
- Current Dossiers are on different Process Flows therefore different implementation dates.

Known infringements today

- Ozone and hydrogen peroxide :using ozone and hydrogen peroxide to create free radicals for biocidal use; is not covered under Article 93
- Ozone for pesticide…..using ozone for pesticide is PT 18 + PT 19
- Ozone for treatment of skin PT1
- Country registrations
  - …..requirement to have LOA to register but companies registered where it is known they do not have a LOA
- Ozone and terpenes to generate a Biocide (not covered under Article 93)

- All reported….not aware of any action taken.

Current tiered approach to enforcement : work within existing framework
ref. HSE uk

- Proportionality
- Targeting
- Consistency
- Transparency
- Accountability

Current tools ref HSE uk

- Allow to remain in non-compliance
  - Informal written notice
- Formal written advice
- Improvement notice
- Prohibition notice
  - Risk of serious personal injury (including animals and the environment)
- Prosecution
  - Prosecution code

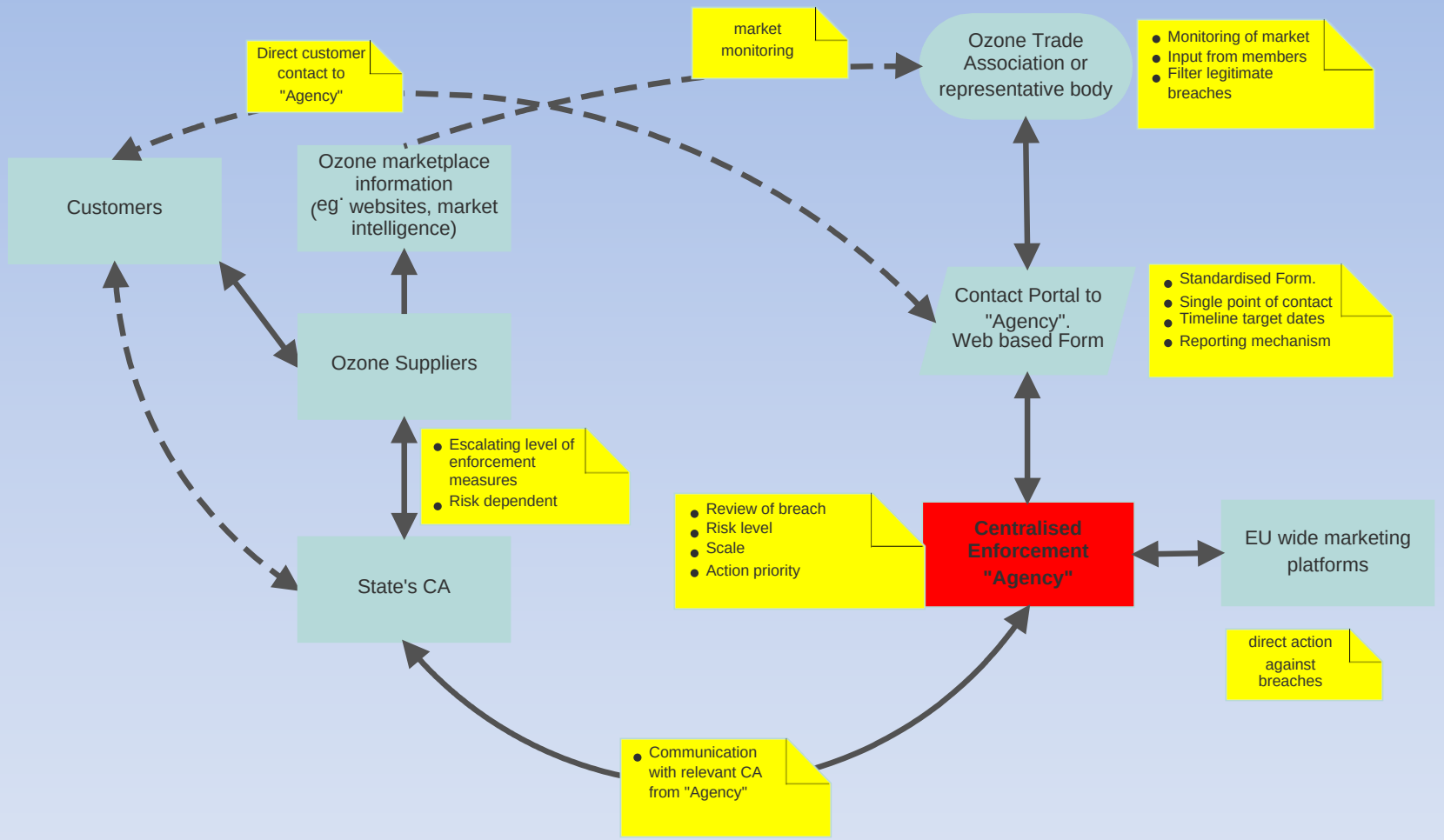
Issues that can be foreseen

- Devices v product
  - A device may be illegal as a Biocide but that same device could be legal if used for non-biocide applications
- Scale of operation
  - For example there are c 400,000 fridges that use ozone
  - More than 200,000 spas use ozone
- Managing ‘platform suppliers’
  - Companies open and close continually (Amazon)
  - Advertisement of the Biocide is outside the EU (Alibaba)
- Approved products are only approved for the registration applied for…could be just country specific

Issues that can be foreseen

- A product can be manufactured within the EU where it's use is illegal but sold outside the EU.
- Cross country movement of devices difficult to track within the EU. A product that is authorised in France can be advertised legally in France but purchased for use in another country.
- Significant number of small businesses will leave it too late due to complexity and cost of process or complete ignorance…..a lot of potential closures. High workload for competent authorities.
- Considerable number of 'orphan' products
- Lack of enforcement will upset many companies who have invested significant time and money
- Devices are sold with warranty periods….liability potentially 12 months before product application deadline
- Devices are often leased…..who has the liability
- Difference in the occupational exposure when used as a Biocide and when not used (factor of 4-10 x depending upon country.

Proposed Information Flow - Central BPR Portal for In situ Device Enforcement Communication



How to work together

- Co-operation and understanding between the consortiums needs to be established / encouraged to create a co-ordinated approach.
- Needs to be a proactive and supported (by regulators) marketing of the impending enforcement. It is known where to go….some weight behind the communication would be beneficial for all.
- The market knows the infringement or will know about it first.
- Individual companies do not want to be involved in company v company disputes re legality.
- Competent authorities have restrictions on available time and costs to carry out investigations.
- One format for all complaints
- One registration point for complaints
- Target time frame for an investigation after initial evaluation / justification of complaint
- An evaluation based upon risk should determine the priority
- The market wants to see action
- A central 'regulatory' office should be established to evaluate complaints

How to work together

- The central authority should forward details to the relevant competent authority where country specific. If cross border or platform based this should be taken up by the central authority.
- Investigations should be registered and tracked and then subsequently reported back to the market.
- Current complaint system is to complicated and un co-ordinated especially cross national for small organisations
  - Eg to complain in France you appear to need to be based in France
  - Moved around different departments as unfamiliar with each Country's system
  - Language issues
  - No response or update on complaints