

## VICE

### Vape at Your Own Risk: Company-Ordered Recalls and the Lack of Regulation in the Canadian E-Cigarette Industry

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On October 17, 2014, Flavour Crafters, one of Canada's largest manufacturers of e-cigarette liquids, received a **26-page report** from a chemical analysis laboratory in Durham, North Carolina. The report summarized testing performed on Flavour Crafters' line of e-liquids, found one of them to contain a chemical linked to a devastating respiratory disease, and led the London, Ontario company to rapidly recall from across Canada over 5,000 bottles of one of its flavours: Groovy Grape.

The recall was not the result of Groovy Grape failing to meet the standards set by consumer protection laws—as Canada has no federal and little provincial legislation tailored to govern the production and sale of e-cigarettes and e-liquids. Rather, Flavour Crafters withdrew its product in accordance with a set of best-practices that member companies of the Electronic Cigarette Trade Association of Canada (ECTA) impose on themselves to try fill the regulatory vacuum left by the federal government and bring scientific scrutiny to an industry where product testing is still not the norm and where producers and consumers alike may be ignorant of what's hiding in those clouds of vapor.

There's a **growing belief** within the medical community that—for smokers—e-cigarettes are a less dangerous alternative to their combustible counterparts. But there is also a great deal that is unknown about the long-term health effects of vaping.

In Canada, however, the legal status of e-cigarettes is just as unclear as their long-run effect on health.

Until very recently, the extent of Canadian government policy around e-cigarettes was contained in a **400-word notice** Health Canada released on March 27, 2009. It stated that e-cigarettes fall under the Food and Drugs Act, that all products within the scope of this act require market authorization from Health Canada, and that e-

cigarettes don't have that authorization.

Six years later, in an email responding to VICE's questions about the legality of e-cigarettes, a Health Canada spokesperson repeated these claims nearly verbatim: "E-cigarette products, including e-liquids, that contain any amount of nicotine or have a health claim fall within the scope of the Food and Drugs Act and require approval by Health Canada before they can be imported, advertised or sold in Canada. Health Canada has not approved any e-cigarette with nicotine for sale; it is not permitted to be sold."

According to Health Canada, this is the law.

But since 2009, despite scores of cease-and-desist letters and tens of thousand of dollars worth of e-cigarettes and e-liquids being effectively turned away at the Canadian border, a number of Canadian e-cigarette companies have stubbornly insisted that Health Canada is wrong about the law. And University of Ottawa law professor David Sweanor says they might be right.

"Just because a government entity says something is illegal, doesn't mean it is," explained Sweanor. "That's not how it works in a constitutional democracy. You can say, 'You're wrong. I'll see you in court.'"

This is just what Canadian e-cigarette companies have done, and Health Canada has not pursued court cases that would force the judicial system to settle indeterminacy around e-cigarettes.

In this legal grey zone Canada's e-cigarette industry has boomed.

In 2013, Sweanor, who studies health policy around nicotine and tobacco products, **estimated that the Canadian e-cigarette market** could be worth \$150-million. Forecasts from investment banks suggest that global sales of e-cigarettes in 2015 may reach \$6.5-billion, up from around \$1.9-billion in 2012, and they are bullish about the future of the industry.

But operating outside the law, with no regulation or government oversight is hard for producers and creates risks for consumers. For

years, many in both camps have been calling for the government to step in.

### **Popcorn-Worker's Lung**

Groovy Grape, like most liquids vaporized in e-cigarettes, was a solution of vegetable glycerin, propylene glycol, and varying amounts of nicotine. Although little is known about the long-run effects of inhaling these substances, in the short run, they are seen as fairly benign. But Groovy Grape also contained a flavouring agent, one that used the chemical diacetyl.

Most people haven't heard of diacetyl, but nearly everyone's consumed it.

The yellow-green liquid is an organic compound that occurs as a natural product of fermentation. Also known as butanedione, diacetyl is one of the two chemicals that give butter its distinctive rich, creamy taste. Health Canada and the United States Food and Drug Administration approve diacetyl for consumption in trace amounts, and it is found on the ingredients list of a wide range variety of foods under the obscurity, "Natural and Artificial Flavours."

Diacetyl is also used in flavourings added to e-liquids, most commonly in sweet ones—a practice that the ECTA is trying hard to end.

Numerous scientific studies—including **several** by the United States Centers for Disease Control and Prevention (CDC) and National Institute for Occupational Safety and Health (NIOSH)—link the inhalation of diacetyl to a disease colloquially known as Popcorn-Workers Lung, for the eight people who contracted the rare malady after working in a Missouri popcorn plant where diacetyl was used as a flavouring.

The disease's medical name is less playful: it's bronchiolitis obliterans.

Bronchiolitis obliterans develops when an irritant inflames the bronchiole, the myriad tiny passageways that allow air to pass from the nose and mouth to the lungs. As the bronchiole try to heal

themselves, scar tissue builds up, further obstructing the flow of air to the lungs. This damage is irreversible. By 2004, four of the eight originally diagnosed workers were on lung transplantation waiting lists.

A **2013 report** from the CDC and NOISH cites diacetyl as the suspected cause of—at least— five deaths and hundreds of injuries from respiratory damage in the Missouri popcorn industry, and **an investigation** by the *Milwaukee Journal Sentinel* suggests that there have been many more.

It is difficult to establish a causal relationship through after-the-fact epidemiological analysis, but diacetyl has been repeatedly shown to cause severe lung damage through animal testing. The introduction of the 2013 CDC and NOISH report states, "Studies involving laboratory animals have demonstrated that exposure to butter flavouring chemicals, and specifically diacetyl and 2, 3-pentanedione, causes damage to the respiratory tract that is consistent with the development of bronchiolitis obliterans."

Few e-liquids have been recalled for diacetyl, but a **2014 study** by the Society for Research on Nicotine and Tobacco found that many contain the chemical.

The study was headed by Konstantinos Farsalinos, a leading researcher on e-cigarettes and doctor at the Onassis Cardiac Surgery Center in Athens, Greece. It tested 159 samples of sweet-flavoured e-liquids from 36 different manufacturers in seven different countries.

It found that 74.2 percent of the liquids contained diacetyl, and nearly half of those contained concentrations that exceeded the safety limit for occupational exposure (five parts per billion) proposed by NIOSH. "Diacetyl is an avoidable risk because—unlike in smoking where the levels of diacetyl, which are several times higher than what we've found in e-cigarettes, are the result of combustion—in e-cigarettes it's present as an ingredient," said Farsalinos.

### **Sour grapes**

Flavour Crafters operates two production labs: one dedicated to mixing batches of e-liquid and one for bottling them. On a daily basis,

these labs pump out between 30 and 50 gallons of e-liquid, which is mixed in one-gallon jugs and separated into ten- and 30-milliliter bottles for retail.

Depending on size, nicotine concentration and volume being sold, a bottle of Flavour Crafters e-liquid will sell for between \$6 and \$20. On average, the company produces between 4,000 and 8,000 of these bottles each day.

Flavour Crafters revenue last year was close to \$3 million, and Joel Verburg, the company's executive director, said that they have experienced nearly 400 percent annual growth every year since they began producing their own e-liquids in 2011.

When Flavour Crafters is mixing one of its e-liquids, each ingredient in every batch is documented with an identification number and the molecular weight used is recorded. The mixing jug is then assigned a batch date and all this information is stored in a database and used to print labels for the retail bottles filled from that batch. This system also serves to precisely track the contents of each bottle.

"We didn't start this detailed, but as we've done it, we've tried to perfect it as much as possible because we want to have full traceability of our products," said Verburg.

As a member of the ECTA, Flavour Crafters is required to submit samples of their e-liquids for testing every six months. In 2013, the ECTA began running these tests, supervised by an independent auditor, through Enthalpy Analytical, Inc., a North Carolina lab that specializes in analyzing gases. ECTA liquids are tested for acetaldehyde, acetoin, diacetyl, formaldehyde, pentanedione, nicotine concentration, acidity, and water content.

In October of last year, when Enthalpy found that Groovy Grape contained diacetyl in levels slightly above the ECTA's "maximum acceptable limit" (100 micrograms per milliliter, a cutoff a little lower than the one NIOSH recommended), Flavour Crafters' tracing system came into action.

Verburg told VICE that his company was able to recover every unsold

bottle of Groovy Grape on the market, soon after it received Enthalpy's report. In a statement (since removed) on the company's website, it urged its clients to return any unused bottles of Groovy Grape for a full refund or exchange them for double the amount of another e-liquid. Flavour Crafters covered all shipping expenses and estimated that the recall cost them between \$10,000 and \$15,000. "There was direct communication with all of our re-sellers to make sure everything was brought back," said Verburg. "We tried to make it really, really appealing for people to return it."

A few Canadian e-liquid retail websites still list Groovy Grape as in-stock and available for purchase. When contacted by VICE, these retailers said that they are no longer selling the flavour and that they have not yet updated their sites to reflect the recall.

Groovy Grape has been on the market in Canada since as early as April, 2012. According to the Flavour Crafters' testing records (**available on their website**), it was first tested for diacetyl in October 2014. However, Verburg said that Flavour Crafters had earlier tested a liquid that was a blend of equal parts Groovy Grape and a tobacco flavored liquid. These tests found no diacetyl.

### **Vape but verify**

The strict production and testing standards of Flavour Crafters and the other 37 members of the ECTA, make these producers anomalous in Canada's large e-cigarette industry.

Making e-liquid is easy: it requires no specialized equipment or knowledge and the basic ingredients are readily attainable. In fact, vegetable glycerin, propylene glycol, nicotine, and a huge variety of flavourings can all be purchased on Amazon.

Home brewing e-liquid is extremely popular and even considered a sort of art by some enthusiasts. The DIY sub-forum on **e-cigarette-forum.com** has 15,213 threads and 244,842 individual posts. At the top of the forum is a disclaimer: "All DIY procedures are done at your own risk."

Although she said that many now well-established companies started this way, ECTA Director Kate Ackerman and owner of Electro Vapors admonished DIY mixing. "It is not OK to produce something for

commercial use in your kitchen, at the table, while the kids are eating Kraft Dinner ... Not having any oversight, not having anyone to answer to, that's not a proper way to produce anything."

Even beyond the home brewers, it is impossible to get an accurate count of how many e-cigarette retailers and e-liquid producers there are in Canada. There is no distinct business type for e-cigarette stores: some are registered as electronics shops, others as personal accessory stores, still others seem not to be registered businesses at all.

Since around 2012, e-cigarette stores have been opening in cities across Canada with rapidity and in a volume reminiscent of the early days of Starbucks. Some of these shops purchase the e-liquids they sell from large producers like Flavour Crafters, but others mix their own liquids, sometimes right in the shop, as a way to increase profit. John Aikman said that when he opened his e-cigarette shop, Vape Lion, in Montreal just over a year ago it was one of four or five devoted e-cigarette retailers in the city. He estimates that there are now closer to 40.

Vape Lion is one of the shops that produce their e-liquid in-house. Aikman purchases the ingredients in bulk and mixes them in a room in the back of his downtown store. When asked about the flavourings he uses and how he guards against diacetyl and other harmful chemicals, Aikman said that he relies on the e-cigarette web forums and guarantees from flavouring companies.

"There is a very strong online community and if anybody finds anything wrong with a particular brand of liquid, then it instantly goes viral," said Aikman, "We just deal with five or six large flavouring companies, and they'll say right out if a flavour contains diacetyl or not."

But guarantees without testing can't always be trusted, and even producers and home-brewers aware of the risks associated with the diacetyl may be ignorant of the fact that their liquids contain it. Flavour Crafters stopped production of one other e-liquid due to diacetyl content. The results from Enthalpy Analytical's first testing of Flavour Crafters liquids showed that their butterscotch contained

1,779 micrograms of diacetyl per milliliter—more than 15 times what was later found in Groovy Grape.

This came as a surprise to Flavour Crafters, who had been purchasing their flavouring from Flavor West, a California flavouring company. According to a statement on Flavour Crafter's website, Flavor West had advertised their butterscotch flavouring as being free of diacetyl, and after being contacted by Flavour Crafters with the test result they removed the diacetyl-free claim from the webpage. Today, the page for butterscotch on the Flavor West's website states, "Independently laboratory tested diacetyl free. Contains 1.074% acetoin."

When contacted by VICE about the 2013 incident with Flavour Crafters and its present testing regime, Flavor West's corporate financial officer Jason Stern said that some of their flavours previously contained diacetyl but it has since been removed. Stern could not give specific dates for when this change was made or during what periods the Flavor West's website stated that their butterscotch flavouring was diacetyl free.

He was also unable to say exactly when Flavor West began having their flavourings tested for chemical content, although he said it was around a year-and-a-half or two years ago, and did not respond to follow-up emails asking for specific dates. Diacetyl was found in Flavour Crafters' butterscotch on June 16, 2013.

Stern declined to tell VICE who is conducting chemical testing for Flavor West.

"If someone is putting our flavouring in their juice, I don't know exactly what's going on with that," said Stern. "I've actually told everybody that if they want to test to see that it's diacetyl free, they need to do a third-party test on their end as well."

Discussing his study on diacetyl in e-liquids, Farsalinos said that a number of other e-liquid producers had been surprised when the test results for their products came back positive for the chemical. As with Flavour Crafters' butterscotch, they had been using flavourings

advertised as diacetyl free.

Both Farsalinos and Ackerman are optimistic that the use of flavourings with diacetyl has declined since the publication of the study, but they also agreed that there is no substitute for testing.

"I think that taught a big lesson to the companies that they shouldn't just accept whatever they hear," said Farsalinos "They must provide test results to prove that the liquids are diacetyl free."

Earlier this month, the House of Commons Standing Committee on Health (HESA) issued the Canadian government's first step towards creating a policy around e-cigarettes since Health Canada ineffectively prohibited them in 2009.

**The HESA report** makes 14 recommendations for government action on e-cigarettes. They include calling for more research funding, a number of measures to guard against children using e-cigarettes, requiring clear labeling of e-liquids, banning vaping in public spaces, and establishing "a new legislative framework ... for regulating electronic cigarettes."

The bi-partisan report does not take a stance on the health effects of vaping or the effectiveness of e-cigarettes for smoking cessation and there is no timeline for turning its recommendations into law.

Nowhere in its 58 pages does the HESA report specify standards for e-liquid testing or mention the word diacetyl.

[http://www.vice.com/en\\_ca/read/a-company-ordered-recall-highlights-the-wild-west-of-e-cigarette-lack-of-regulation-in-canada-289](http://www.vice.com/en_ca/read/a-company-ordered-recall-highlights-the-wild-west-of-e-cigarette-lack-of-regulation-in-canada-289)