## China's e-cigarette boom lacks oversight for safety

By David Barboza
 The New York Times

• Dec 13, 2014 Updated Dec 14, 2014

E-cigarettes made at Iciga, one of hundreds of small factories producing them in Shenzhen, China, March 25, 2014. Almost all the world's e-cigarettes are made without oversight, and experts say counterfeiting, or sloppy manufacturing could account for some of the hazards seen in the devices. Sim Chi Yin/The New York Times

A worker tests e-cigarettes just off the production line at Joytech, one of hundreds of such producers in Shenzhen, China, March 24, 2014. Chinese manufacturers are expected to export more than 300 million e-cigarettes this year, but initial confusion over how to categorize the new products means there is virtually no regulatory oversight of a chaotic industry rife with counterfeiting. Sim Chi Yin/The New York Times

SHENZHEN, China — In a grimy workshop, among boiling vats of chemicals, factory workers are busy turning stainless steel rods into slender tube casings, a crucial component of electronic cigarettes. Not long ago, Skorite Electronics was a tiny firm struggling to produce pen parts. Today, it is part of an enormous — and virtually unregulated — supply chain centered here that produces about 90 percent of the world's e-cigarettes.

This year, Chinese manufacturers are expected to ship more than 300 million ecigarettes to the United States and Europe, where they will reach the shelves of Wal-Marts, 7-Eleven stores, gas station outlets and vaping shops.

The devices have become increasingly popular, particularly among young adults, and yet hundreds of e-cigarette manufacturers in China operate with little oversight. Experts say flawed or sloppy manufacturing could account for some of the heavy metals, carcinogens and other dangerous compounds, such as lead, tin and zinc, that have been detected in some e-cigarettes.

One study found e-cigarette vapor that contained hazardous nickel and chromium at four times the level they appear in traditional cigarette smoke; another found that half the e-cigarettes sampled malfunctioned and some released vapor tainted with silicon fibers.

There have also been reports in the United States of e-cigarettes that exploded after a lithium ion battery or electric charger overheated, causing burns.

"We need to understand what e-cigarettes are made of," says Avrum Spira, a lung specialist at the Boston University School of Medicine, "and the manufacturing process is a critical part of that understanding."

A review by *The New York Times* of manufacturing operations in Shenzhen found that many factories were legitimate and made efforts at quality control but some were lowerend operations that either had no safety testing equipment or specialized in counterfeiting, often with cheaper parts. *The Times* visited several such workshops in Shenzhen, including a counterfeiting shop set up in a garage and another that displayed a knockoff of an e-cigarette brand called "Russian 91%," which the factory boss said was destined for the United States.

The e-cigarette industry in China has developed differently from other industries, like toys, apparel and smartphones, where global brands outsource their manufacturing here but monitor and enforce quality control standards. Chinese companies were the first to develop e-cigarettes, and that happened in a regulatory void. In the United States, the Food and Drug Administration has just begun to move toward regulating e-cigarettes,

working on rules that would force global producers, in China and elsewhere, to provide the agency with a list of ingredients and details about the manufacturing process.

But analysts say setting those rules and new manufacturing guidelines could take years. In the meantime, Chinese factories are quickening the pace, hoping to build profits and market share before regulatory scrutiny arrives and most likely forces many e-cigarette makers to close.

"This is really a chaotic industry," says Jackie Zhuang, deputy general manager of Huabao International, a Chinese tobacco flavoring company in Shanghai and an expert on China's e-cigarette market. "I hope it will soon be well regulated."

## **Ground zero for e-cigarettes**

In a 5-square-mile area in the northwestern part of Shenzhen called Bao'an, in a district packed with industrial parks, there are believed to be more than 600 e-cigarette producers, and many more component suppliers selling bulk orders of tube casings, integrated circuit boards, heating coils and lithium ion batteries, the essential components of the e-cigarette. If you are a manufacturer in Shenzhen and need 50,000 baked-metal casings, a local manufacturer can supply them for about \$25,000 and have them delivered within hours.

Unlike the counterfeiters' shops, the largest Shenzhen e-cigarette manufacturing operations are relatively clean, with rows of workers seated on plastic stools along a fast-moving assembly line.

In 2004, a Chinese pharmacist named Han Li helped develop the e-cigarette, which was then sold through his company, Beijing Ruyan. Other manufacturers soon followed, and by 2009, as e-cigarettes became more popular in the United States and Europe, more factories opened.

Global tobacco giants that have entered the e-cigarette market are also manufacturing in China, and they insist they are doing so with stringent controls.

Altria, formerly known as Philip Morris, sells the e-cigarette brand MarkTen. In a statement, Altria said: "MarkTen is manufactured in China for Nu Mark" — Altria's e-cigarette subsidiary — "by an established manufacturer of e-cigarettes, which is following Nu Mark's design specifications and quality control requirements" with "detailed quality-control measures."

## **Troubled manufacturing**

Smaller manufacturers, though, are more representative of the ethos here. Tiny startup factories buy components from suppliers, set up assembly lines and hire low-skilled migrant workers to snap, stamp, glue and solder the e-cigarette components together.

"In the e-cigarette market, you don't need big capital — that's why there are now so many manufacturers here," said Qiu Weihua, the founder of Joyetech, a large Chinese firm that is trying to distinguish itself as a high-quality producer of e-cigarettes. The firm, for example, employs testers who vape and check for flaws. "The big challenge is how to make a quality product."

The e-cigarette makers, many run by young entrepreneurs, have found markets overseas, using online platforms like <u>Alibaba.com</u>. But occasionally, a U.S. businessman like Yaniv Nahon simply shows up at the factory gate. In 2010, Nahon, then 29, grew tired of selling e-cigarettes at a mall kiosk in South Florida and decided to produce his own line called Vapor 123.

"A lot of our products come in smaller orders using express mail service, no questions asked," Nahon said in an interview at a factory called Jomo in Shenzhen. "Importing this into the U.S. isn't difficult."

Scientific studies hint at a host of problems related to poor manufacturing standards. A study published last year in the open access online journal *PLoS* One found the presence of tin particles and other metals in e-cigarette vapors and said they appeared to come from the "solder joints" of e-cigarette devices.

Another study of nearly two dozen e-cigarettes bought in the United States found large amounts of nickel and chromium, which probably came from the heating element, another suggestion that poorly manufactured e-cigarettes may allow the metals to enter into the e-liquids.

"We've found on the order of 25 or 26 different elements, including metals, in the ecigarette aerosols," says Prue Talbot, a professor of cell biology at the University of California, Riverside, and co-author of several of the studies. "Some of the metal particles are less than 100 nanometers in diameter, and those are a concern because they can penetrate deep into the lungs."

Health advocates say they are troubled by a history of food and drug safety scandals in China, such as when manufacturers substituted diethylene glycol, an industrial solvent, for the sweetener glycerin when making toothpastes and cough medicine. That led to reports of more than 350 deaths in Panama, China and other countries in 2006 alone.

The risk of diethylene glycol showing up in e-cigarettes is real. In 2009, the FDA issued a warning about the potential health risks associated with e-cigarettes, saying laboratory studies of some samples had found the presence of toxic chemicals, including diethylene glycol, which is used in antifreeze.

## **Pressure on regulators**

Eventually, analysts say, the FDA could be compelled to certify e-cigarette factories and the manufacturing standards. But that could be months if not years away.

The agency, however, is under pressure from public health advocates and medical experts.

"What if someone in China buys nicotine, solvents and flavorings, but the source of these ingredients is unknown and they're manufactured with impurities?" says Maciej Goniewicz, a toxicologist at the Roswell Park Cancer Institute in Buffalo, N.Y. "That could put consumers at risk."

Keenly aware that tighter regulations are on the horizon, Shenzhen e-cigarette makers are beginning to establish overseas branches to make e-liquids — the substance that is heated, then turned into vapor and inhaled. The FDA does not yet have standards for e-liquids, but many of the Chinese companies say they make them in labs in the United States that have passed FDA quality-control standards.

"I can tell you that all of our e-liquid is manufactured, bottled and filled here in the United States," the chief executive at Mistic e-cigarettes, John J. Wiesehan Jr., said in an email. "Our liquid never leaves the U.S. We get no e-liquid from China."

Big e-cigarette makers in the United States have begun to move manufacturing to the United States or Europe. Global tobacco companies are doing likewise. And some Chinese manufacturers, including Joyetech, are also moving their production facilities to the West.

"A lot of people don't trust the air or water in China," says Qiu, the boss at Joyetech ecigarettes, "so why would they trust our e-liquid?"