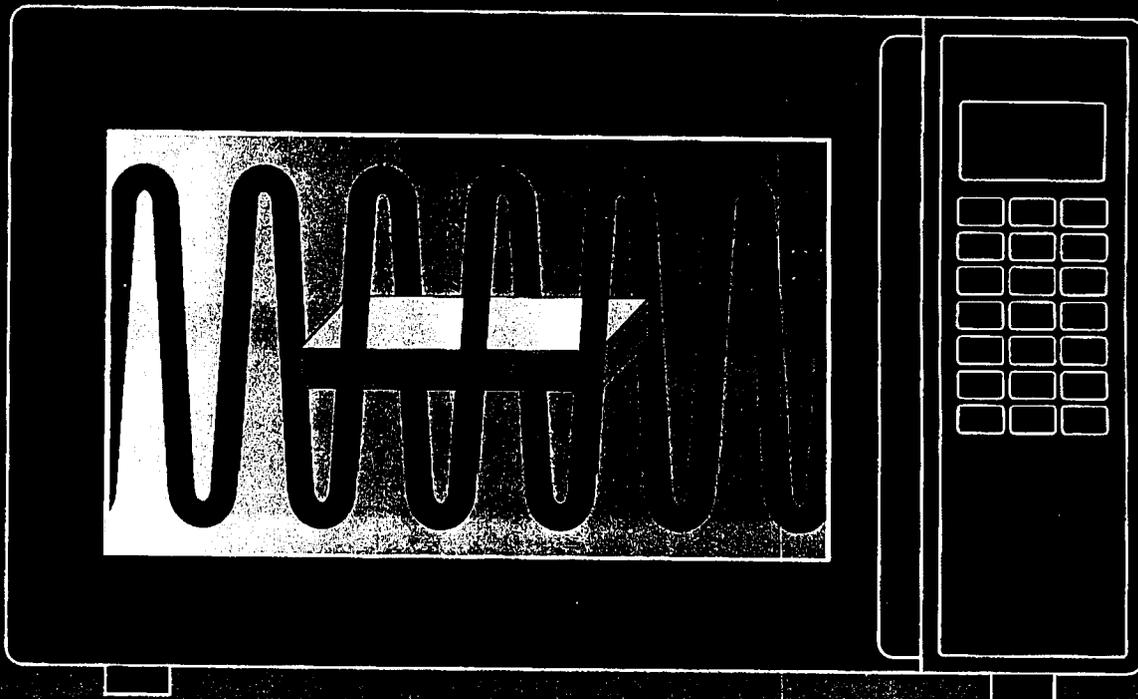


**This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.**

# Keeping Up with the Microwave Revolution

by Dixie Farley



**M**icrowave oven cookery is on a roll—and the Food and Drug Administration is working to keep up.

Sales of microwave-packaged foods are expected to reach \$3 billion by 1992, up from \$900 million in 1987 and \$53 million in 1983. To capture this expanding market, industry has devised numerous packaging innovations. For instance, microwave-absorbing "heat susceptors" induce high temperatures to provide popcorn in a jiffy or brown and crisp pizza and other foods, and plastic "dual-ovenables" are prepared for use in either the conventional or microwave oven.

But the way FDA sees it, the revolutionary technologies producing these niceties were applied before the agency's regulations were ready for them. Although both types of packaging may be manufactured with components that comply with various food additive re-

quirements, FDA has not evaluated the safety of all these materials at temperatures above 300 degrees Fahrenheit. Yet, heat susceptors sometimes exceed 500 F, and dual-oven plastic trays in conventional ovens are usually used at 350 F to 400 F.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has no information to show a health risk. The center is concerned, however, that such high temperature use of these materials may cause packaging components such as adhesives, polymers, paper, and paperboard—known as indirect food additives—to migrate into food at excessive levels.

#### Indirect Additive Safety

Any new indirect additive used in making food-packaging materials must have FDA's approval before marketing. The manufacturer must provide scientific

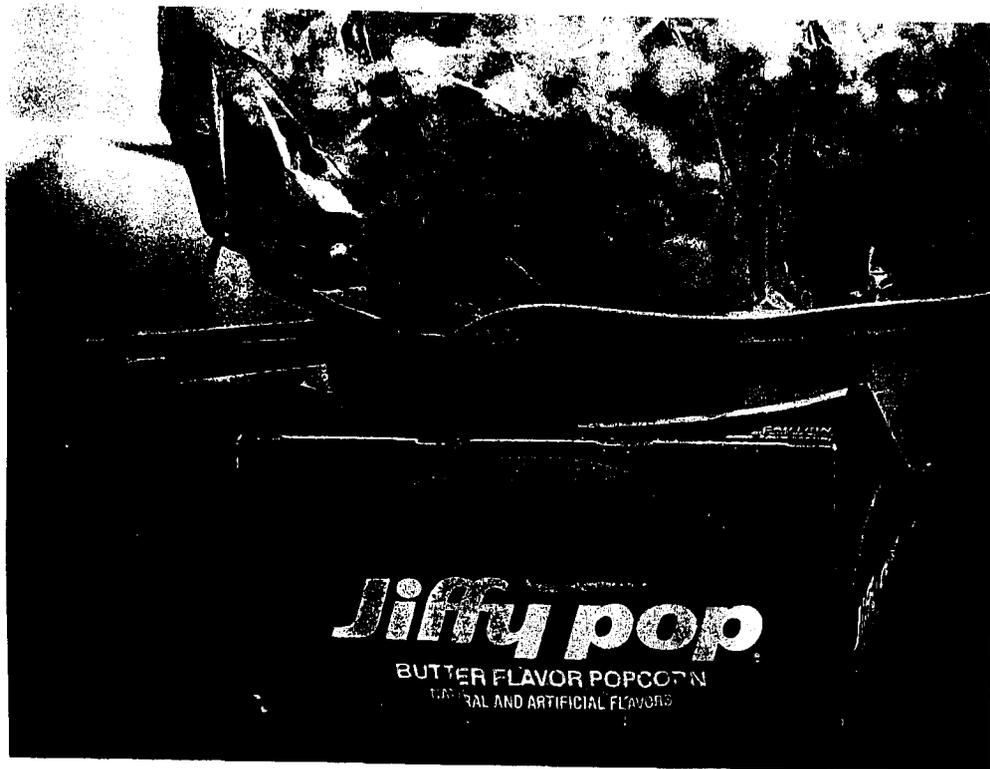
data proving that the additive is safe for its intended use. Test results, for instance, must show the nature and levels of the packaging materials, the components likely to migrate, and any potential hazards. The analytical procedures must reliably predict migration levels during the proposed uses. Approval takes the form of a regulation specifying the permitted conditions of safe use, such as temperature and type of food.

While these regulations describe permitted use conditions for packaging materials, they don't limit uses to a specific manufacturer. As long as other firms use an approved additive according to regulations, further FDA approval is unnecessary.

The agency has been regulating indirect food additives since 1958, with the result that most of these regulations predate the technologies behind microwave heat-susceptor and dual-ovenable pack-

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*Above, high temperatures generated by the popcorn heat susceptor pad caused it to burn. At right, Timothy Begley of FDA's indirect additives laboratory uses a susceptor pad for browning pizza. In testing products such as these, Begley and colleagues found that packaging components had migrated into the food.*

*(Continued from page 34)*

aging. Because FDA could not foresee the extreme heat produced by these innovations, it did not initially specify temperature for migration testing of many indirect additives. In September 1988, FDA issued new recommendations for migration testing protocols, including those for high heat applications.

#### **A Possible Problem?**

FDA's first hint that there might be a problem with heat susceptors came in the winter of 1987-1988 from some of its employees' personal experiences with the new packaging. During the cold weather, like many people, the staff of the CFSAN indirect additives laboratory enjoyed popcorn parties in their homes in front of the television set.

"We were talking at work about getting burn-through in popcorn bags we had used in our microwave ovens at home," says Henry Hollifield, Ph.D., director of the laboratory. "So, we brought several of these packages into the lab, popped the corn, and tested the temperatures. The heat-susceptor portion of the packages got as hot as 500 degrees F."

The food-contact surface of heat-susceptor packaging is usually a metalized

polyethylene terephthalate (PET) film laminated to paperboard with adhesive. This metalized film absorbs the microwave energy in the oven and, with most of the microwaves absorbed, the package becomes a little "frying pan" that actively participates in the cooking. (See "What Makes the Microwave Run?" page 37.)

Initial CFSAN studies indicated that the PET film is not a protective barrier between the food and the outer packaging and that the PET itself contributes migrants to the food. Three minutes of microwave heating with susceptors caused more than 70 percent of PET components, called oligomers, to migrate into the corn oil used in the studies to simulate food. Six minutes' heating caused 95 percent migration.

Because susceptors help cook the food, they're known as active packaging. Only a small percentage of microwave packages use susceptors. The vast majority use passive materials, which are transparent to microwaves; the waves pass through the materials to cook the food. These materials are heated solely from the cooking food, so they don't get much hotter than the food.

Still, even some passive packaging, such as dual-ovenables, will produce mi-

gration at high temperatures. When CFSAN laboratory personnel heated PET-containing dual-oven trays in a conventional oven at 350 F—following package instructions—they detected migration of the oligomer constituents at levels similar to those found with susceptors. Such migration is possible because foods must be cooked in conventional ovens for a longer time than in microwave ovens and because many conventional ovens heat higher than the temperature setting. (For example, an oven set at 350 F could in fact be heating at 400 F.)

Migration from the packages may turn out to be harmless. But CFSAN as yet doesn't have enough safety data to evaluate uses at these high temperatures.

#### **CFSAN Goes to Industry**

As a result of the indirect additives laboratory's initial findings, CFSAN held a public meeting on Sept. 22, 1988, in Washington, D.C., primarily to discuss the center's need for more information to evaluate the safety of heat-susceptor materials used at temperatures much higher than those set by existing regulations. CFSAN requested the following types of safety data on susceptors:

- chemical components used to make heat-susceptor packaging
- breakdown products formed in worst-case use conditions
- migration data from tests during likely

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## Microwaving Tips

More than a third of marketed raw chickens are contaminated with *Salmonella* bacteria, a common cause of food poisoning. Two types of worm, *Trichinella spiralis* in pork and *Anisakis* larvae in fish, can survive in undercooked food to cause illness. Thorough cooking of meat, poultry and fish is vital to prevent such food-borne illness.

The U.S. Department of Agriculture, which oversees the safety of meat and poultry, offers the following advice for safe cooking with the microwave oven:

- Arrange meat and poultry pieces uniformly in a covered dish so steam can help kill bacteria and promote uniform heating. Stir the food and turn the dish

several times. Observe standing time. Use a microwave temperature probe or check with a meat thermometer to ensure a safe temperature—160 degrees Fahrenheit for red meat, 180 F for poultry. Check in several spots.

- Cook stuffing separately from poultry.
- De-bone a roast. Turn it several times during cooking. Check its temperature for safety. Let the meat stand wrapped in foil at least 20 minutes for steam to complete the cooking.

Other sensible precautions when using the microwave are:

- Discard a casserole food if it was forgotten and left for more than two hours in the microwave after thawing. Subsequent ordinary cooking won't destroy some harmful bacteria that could form.
- Apply the practices of steaming, turning the dish, and observing standing time when cooking fish and other foods.
- Don't use the microwave for deep-

frying, canning, or heating baby bottles. These applications don't allow adequate temperature control for safe results.

- Stay with the oven when microwaving popcorn, for heat buildup can cause a fire. Time heating per instructions but lean toward the shorter time (some ovens can scorch popcorn in two minutes).
- Don't dry or disinfect clothing or other articles in the microwave because of the risk of fire.
- Use only microwave-safe utensils. Hot food melts some plastics, such as margarine tubs, causing migration of package constituents. It's a good idea to use glass for fatty foods, which get particularly hot, though not all glass and ceramics are microwave-safe. Here's a quick test for glass: Microwave the empty container for one minute. It's unsafe for the microwave if it's warm; it's OK for reheating if it's lukewarm; and it's OK for actual cooking if it's cool.

—D.F.

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## How Safe Is Your Oven?

Properly used, a microwave oven is extremely safe. Under authority of the Radiation Control for Health and Safety Act, FDA's Center for Devices and Radiological Health ensures that microwave ovens made after 1971 meet a radiation safety standard requiring:

- two independent interlock systems to stop microwave production the moment the latch is released or the door is opened
- a monitoring system to stop the oven if either or both of the interlocks fail.

The standard limits microwave leakage to 5 milliwatts per square centimeter (mW/cm<sup>2</sup>) at about 2 inches from the oven—a very low level of exposure. (Medical applications use up to 1,000 mW/cm<sup>2</sup> without apparent ill effects.) FDA tests have shown that *actual* microwave emission is under 2 mW/cm<sup>2</sup>.

Moreover, exposure decreases dramatically with distance. Someone 20 inches from the oven would receive only about one one-hundredth of the radiation

as a person 2 inches away. There is no radiation residue after microwave production stops. The whirring noise some ovens make after the door is opened is the fan and has nothing to do with radiation.

To make sure the standard is met, FDA tests microwave ovens in manufacturing plants and its own laboratories. According to Joanne Barron, chief of CDRH's television acoustic and microwave products branch, recent tests by state health officials, FDA field inspectors, and laboratory analysts from the Winchester Engineering and Analytical Center in Massachusetts have very rarely detected an oven that emits leakage above the standard. She explains, "We get two to 20 complaints a year, but most turn out to be false alarms. When there is a real problem, it's usually due to abuse of the oven or improper servicing."

To be sure radiation levels from a microwave oven remain as low as possible, consumers can take these steps:

- Don't use an oven if an object is caught in the door or if the door doesn't close firmly or is otherwise damaged. If you have an older model oven with a soft mesh door gasket, check for deterioration, which would require servicing.
- If you suspect excessive microwave

leakage, contact the manufacturer, a reputable servicing firm, the local state health department, or the nearest FDA office. FDA has found the inexpensive home microwave-testing devices that are available to be generally inaccurate.

- Don't operate an empty oven if the instruction manual warns against this. In some ovens, the magnetron tube can be damaged by unabsorbed energy.
- If there are signs of rusting inside the oven, have the oven repaired.
- Clean the door and oven cavity—the outer edge, too—with water and mild detergent. Do not use abrasives such as scouring pads.
- Follow the manufacturer's instruction manual for recommended operating procedures and safety precautions.
- Be sure children who use the microwave can do so safely.

There previously was concern that electromagnetic emissions from a microwave oven could interfere with a heart pacemaker. Modern pacemakers are shielded against such interference, but some older models may still be adversely affected by proximity to a microwave oven. If in doubt, check with your doctor. ■

—D.F.

## What Makes the Microwave Run?

Microwaves are a form of electrical and magnetic energy moving through space. They are useful in cooking because they're absorbed by foods but reflected by metal and because they pass through glass, paper, plastic, and similar materials.

Produced by a magnetron electron tube, microwaves bounce about inside the metal oven until absorbed by food. They cause food molecules such as water, a very efficient microwave absorber, to vibrate and thus produce heat to cook the food. That's why foods high in water content, such as fresh vegetables, can be cooked more quickly than other foods. Microwaved foods retain more vitamins and minerals than foods cooked other ways because microwaving takes less

time and doesn't require much additional water.

Though microwaves produce heat directly in the food, they really don't cook food from the inside out, says Joanne Barron, who heads the television acoustic and microwave products branch at FDA's Center for Devices and Radiological Health. "With thick foods like roasts," she says, "microwaves generally cook only about an inch of the outer layers. The heat is then slowly conducted inward, cooking along the way."

An area of a food where there is increased moisture will heat more quickly than other areas. So, when heating up a jelly roll, for instance, it's a good idea to let the food stand after cooking for a minute or two until the heat disperses

throughout. To promote uniform cooking, recipes for the microwave usually include directions such as "turn the food midway through cooking" and "cover and let stand after cooking."

As a rule, it's not good to use metal pans made for conventional ovens or aluminum foil because the reflected microwaves cause uneven cooking and could even damage the oven. However, some new metal cookware is specially configured for use in microwave ovens. Barron says these pans are safe, provided instructions for use are carefully followed.

Some oven models have a protector on the magnetron tube to allow use of a small amount of metal, such as meat skewers or strips of foil over chicken wings and legs. The instructions that come with each microwave oven tell what kinds of containers to use and how to test for suitability for use.

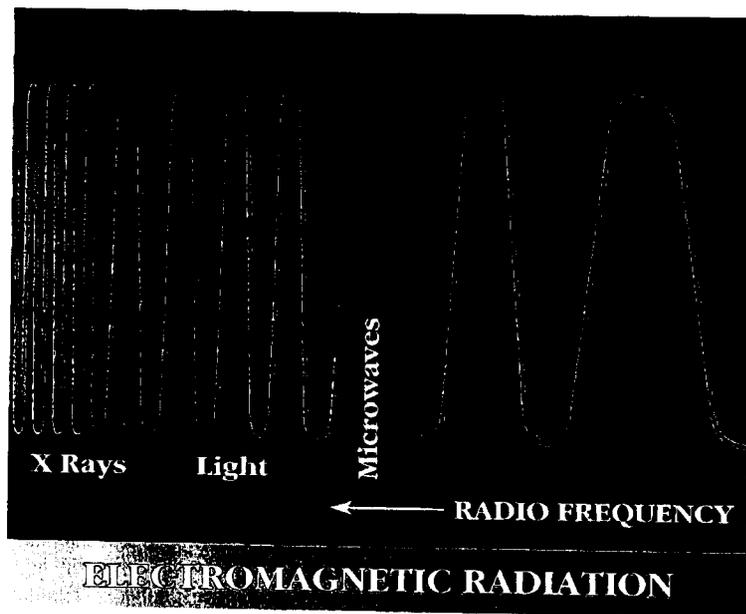
Microwave oven output also given in an oven's packaging literature, can vary from 200 watts to around 750 watts—the bigger the oven, the greater the output tends to be. Ovens with fewer watts take longer to cook—sometimes as much as 30 percent more time. Some microwave-packaged foods are labeled with heating directions by wattage.

The Campbell Microwave Institute suggests the following test for gauging output:

- Fill a glass measuring cup with exactly 1 cup of tap water.
- Microwave, uncovered, on "high" until water begins to boil.

<b>If boiling occurs in:</b>	<b>wattage is:</b>
less than 3 minutes	600 to 700
3 to 4 minutes	500 to 600
more than 4 minutes	less than 500 watts

—D.F.



*Microwaves are within the radio frequency band of electromagnetic radiation. They should not be confused with x-rays, which are more powerful.*



*Consumers visiting their favorite carry-out restaurants may soon be given their food in Nuke-It, a new self-venting, disposable rewarming unit that recently went on the market. Also new: ovens like this one with a choke system built into the door to prevent leakage, eliminating the need for the older soft mesh gaskets, which can deteriorate.*

*(Continued from page 36)*

maximum time and temperature conditions

- toxicological data for migrant substances
- information about use conditions such as heating times, temperatures, and types of food to be used in the packages.

In response, the Society of the Plastics Industry and the National Food Processors Association jointly sponsored a committee to obtain the information and to work with the American Society for

Testing and Materials to develop standardized tests for susceptor packaging.

On Sept. 8, 1989, CFSAN published a notice in the *Federal Register* specifying the data industry is required to provide and the deadlines for these submissions. CFSAN will use the information to make decisions about amending indirect food additive regulations.

#### **And the Heat Goes On**

The story continues to unfold.

Members of the food-packaging industry had claimed CFSAN's use of corn oil

simulant rather than food in the laboratory tests did not represent actual use conditions. So, during the spring and summer of 1989, CFSAN chemists developed analytical methods to measure the extent of migration of heat-susceptor packaging components into food. They tested different kinds of susceptors and looked at pizza, popcorn, waffles, and breaded products such as fish sticks. In a meeting with the industry's ad hoc committee on Sept. 25, CFSAN released findings about one sample—french fried potatoes: 5 to 7 parts per million (ppm) of PET oligomers and 15 ppm of diethylene glycol dibenzoate (an adhesive component) had migrated from the film to the food. Though that was only one example, it showed that susceptors used under high heat conditions can cause migration and demonstrated that CFSAN now has test methods to show this actually occurs in food.

While current reports to CFSAN show no health hazard due to substances migrating from heat-susceptor and dual-ovenable packaging, the center will continue working with industry to obtain more conclusive safety information. CFSAN also has contracted with an outside firm to examine migration of packaging components into food. ■

*Dixie Farley is a staff writer for FDA Consumer.*

## **For More Information**

Questions about microwave ovens or food packaging can be directed to the nearest FDA office listed in the telephone book. Questions about cooking poultry and meat in a microwave oven should be directed to USDA by calling its food safety hot line, 1-800-535-4555 (202-447-3333 in the Washington, D.C., area), 10 a.m. to 4 p.m. weekdays or by writing to The Meat and Poultry Hotline, USDA-FSIS, Room 1165-S, Washington, D.C. 20250.

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