

A top-down photograph of a fresh salmon fillet on a dark slate surface. The salmon is garnished with fresh herbs, black pepper, and lemon slices. Surrounding the salmon are other fresh ingredients like rosemary, red chili peppers, and celery. A semi-transparent white box is overlaid on the center of the image, containing the title and author information.

# ENVIRONMENTAL MONITORING PROGRAM: A STEP BY STEP GUIDE

A COLLECTION OF ARTICLES BY **JACK VAN DER SANDEN**

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# JACK VAN DER SANDEN



Jack van der Sanden is an international food safety advisor. He has been part of the global food industry for over 30 years.

After obtaining a food technology degree in The Netherlands, Jack joined the food industry as production supervisor. He migrated to New Zealand in 1990, where he obtained a post-graduate diploma in dairy science and technology at Massey University.

Over the years, he rose through the ranks and ended-up managing production, technical and food safety & quality teams. This cross-functional exposure enabled him to find pragmatic solutions, that strengthened food safety and quality systems in different multinational organizations.

During his career, he has not only advised small and medium-sized businesses in the food industry in New Zealand, but has also managed international consultancy projects in the United States, Europe and China. His expertise has opened many doors for him, from leading training in food safety and quality to mentoring many professionals in the food industry around the world.

During the last 10 years, he has specialised in Environmental Pathogen Management (EPM) and advised food industries in the design of preventive and effective EPM programs.

# ENVIRONMENTAL PATHOGEN MANAGEMENT: WHY DO YOU NEED ONE?

Jack van der Sanden has partnered with BioMérieux, and written a short **series of articles about environmental pathogen management in the food industry**.

We are pleased to give you access to this mini-series of five articles. In this first article, Jack outlines the reasons **why you should implement an environmental pathogen management program** in your food plant.

Being aware that the budget is an important factor for companies, **Jack seeks to convince you that environmental pathogen management is essential** for your food plant and can be cost-effective.

I'm really excited BioMérieux is sharing this short series of articles about environmental pathogen management in the food industry. I have a real passion for this topic and after visiting hundreds of food plants around the world, it is clear to me that a sound environmental pathogen programme can protect your product, your customers and ultimately, your business.

Of course, being pragmatic, I'm also well aware that running an environmental pathogen programme costs money and I fully appreciate that if you run a food business, you want some justification for this expense.

So, let's start with why!

### 1. Pathogens are still the number one threat to the global food industry

If you follow food safety news around the world, it will become clear that the most harmful food safety incidents are all related to pathogen contaminations. In 2017, a food company in South Africa set a dubious record: more than 200 people died from eating a Listeria contaminated pre-cooked sausage. This is the largest number of fatalities linked to a single product in global food poisoning history.

Let's put this in perspective; with 4.1 billion passengers taking to the air, only 44 people died in the global aviation industry in the whole of 2017. So, if these trends continue, it may become riskier to eat a meal than to get on a plane. It possibly already is.

In 2018, we have had E coli in lettuce (US), Listeria in rock melons (Australia), Salmonella in infant formula (France) and Listeria in frozen vegetables (everywhere). Looking at this list, there's something else: the products involved in food poisoning outbreaks are changing. When I started my career in the food industry (which, admittedly, is a while ago), products like frozen vegetables and rock melons were definitely not considered a pathogen risk.

### 2. An environmental pathogen programme works

Monitoring your food plant environment for pathogens will give you an early warning, before your product and your customers are affected. We only have to read some investigations by the USFDA to realise that in several serious food poisoning incidents, the pathogen in the product had been found in the factory environment, before any consumers fell ill.

Take company X, a small soft cheese manufacturer in Florida. In 2015, 20% of their food contact surface swabs for Listeria came back positive. Unable to get on top of this contamination, they continued production and people started getting sick from their cheese in 2016.

The timeline in this case (serious environmental contamination in 2015 and consumer illness in 2016) shows that an environmental pathogen monitoring programme can give us plenty of warning and time to act.

For me, a positive environmental sample is a gift. It means we can start investigating, look for the root cause and strengthen our systems and controls, before any real damage happens.

### 3. Your food business is more exposed than ever

New diagnostic developments in microbiology have made a real difference in the investigations of food poisoning outbreaks. Investigators are now using a technology called Whole Genome Sequencing (WGS), which can establish a "hard" link from the patient to the food product all the way back to the manufacturing plant. Once your name is out there, social media will be very quick to link your manufacturing plant to your products and the wider consumer market.

Even if your company is not involved, consequences of a food poisoning outbreak can be devastating. The E. Coli outbreak in Romaine lettuce in the Yuma district in the US, caused the whole market segment for this lettuce to drop by almost 45% (WSJ, 30 May 2018). I believe food safety is pre-competitive and knowledge should be shared between food companies; because a food category is only as good as its weakest link.

There is also a global drive to focus on prevention. This is a good thing! The introduction of the Food Safety Modernisation Act (FSMA) in the United States has seen a dramatic increase in the number of environmental pathogen swabs in food factories. Considering FSMA also applies to importers, these US food regulations are starting to drive the expectations and standards in other parts of the world as well.

Finally, one of the main drawbacks of pathogen testing has disappeared. In the past, we had to wait for five days for a Salmonella result and many FMCG food manufacturers were not in a position to store their finished product for this amount of time. Fortunately, new diagnostic technologies, like Gene-Up from BioMérieux, can give you a valid pathogen result within 24 hours. It's great we no longer have to wait for the bugs to grow.

So, that was the why!

If you are a food manufacturer, environmental pathogen management is a useful preventive tool and becoming increasingly important. For the best protection, the design of your programme is key and over the next four articles I will discuss:

- The dangers of testing for pathogens,
- What pathogens to look for,
- How to plan your pathogen hunt and
- What to do, if you find a pathogen in your plant.

I hope the series will help you with the pathogen controls in your food business. Because, like a smoke alarm, an effective environmental pathogen programme will warn you, give you "peace of mind" and a good night's sleep.

— Jack

# ENVIRONMENTAL PATHOGEN MANAGEMENT: PATHOGEN TESTING IS DANGEROUS

In this second article from our series about environmental pathogen management in the food industry, Jack van der Sanden exposes some potential mistakes companies make, **when embarking on pathogen testing.**

When it comes to pathogens, an error is usually dramatic and can be very costly to your business. Jack reminds us that we have to expect the unexpected, avoid unnecessary recalls and that pathogen testing can be dangerous if we don't follow some basic rules.

Following my first article, I hope you are all very excited about environmental pathogen monitoring. So it's time to dampen some of that excitement and ring some warning bells! You see, before you start swabbing your plant, it pays to reflect on some global lessons learned: **pathogen testing can be dangerous!**

The impact of a positive pathogen result is dramatic and can be very costly to your business. If a pathogen is found in your product, you have to make a very quick decision about that product, as it can no longer be sold. If a pathogen is found in your factory environment, you may still have some time, but it often leads to a right panic.

So, before we pull out our swabs, I think it's useful to reflect on some of the dangers with pathogen testing.

### The "false alarm"!

I sometimes get asked how to deal with a "false positive" result. A reasonable question, considering the major business impact I have just mentioned. Interestingly, I almost never get asked what to do about a "false negative" result. I think this has to do with a human bias: If we get a result we expect (i.e. no pathogens), we do not tend to challenge the outcome.

Both "false" results do happen, and the consequences are dramatic either way. It could be argued that whilst a "false positive" is expensive due to product loss, a "false negative" is worse, as contaminated product is released into the market. Take the 2017 infant formula contamination in France. The company stated that a large number of their samples tested negative for Salmonella. This would have given them a false sense of security and only when babies started falling ill, did they realise something was seriously wrong.

My only answer to the "false alarm" is this: in order to minimise the risk of a false pathogen result, testing for pathogens should only be conducted with an accredited method. In addition, sampling and sample handling (in your food plant as well as in the laboratory) needs to be very well controlled and you should consider using an accredited laboratory for this reason.

During my global travels, I have seen food company laboratories, with no formal accreditation, testing for pathogens like any other quality parameter. To me, this is asking for trouble because in the end, a pathogen result will stand! Even if you have every reason to doubt the result, there is no recourse.

### The "Russian roulette" test!

I understand working capital and shelf-life are important considerations for any business and moving stock quickly is key, particularly for FMCG manufacturers.

This can sometimes lead to an interesting situation where product is shipped before the final product test results are known. In the case of pathogen tests, this is like playing "Russian roulette". You essentially shoot yourself in the foot if the product has gone and

the pathogen result comes back positive.

As mentioned before, there is only one course of action for a positive product result and if the product is in the market, this means: recall! If the product is still in our control, we can block the contaminated food batch and prevent public exposure. We have to expect the unexpected! Once the product has been released into the market, our window for pathogen verification testing has closed.

Fortunately, new accredited rapid test methods have dramatically reduced the test turnaround times for pathogens and we no longer have to wait for three to five days to get a result.

### The "ticking timebomb"!

This situation occurs when factory management starts accepting a low and sporadic level of positive environmental detects as the "new normal" (another human bias). It goes something like this: positive detect – let's clean; three months later: positive detect – let's clean; two months later: positive detect – let's clean and on and on it goes! You get the picture!? Unfortunately, a persistent low level of environmental pathogen detections is not normal!

Considering the difficulty of recovering and finding actual pathogens in your factory environment, repeat hits only mean one thing: you have a contamination somewhere and could be sitting on a ticking timebomb.

### "We do not know, what we do not know"!

Finally, a personal lesson! I have been in the food industry for over 30 years and this comes at a price: I have a tendency jumping to conclusions based on experience (I suspect I'm not alone). This all changed in 2015 with ice cream.

You see, I never thought of ice cream as a risky food (it's frozen – what can go wrong!?). Hence, I was quite relaxed about the lack of environmental pathogen monitoring in some ice cream factories. That was of course, until the 2015 contamination incident in the USA, when people got sick and died from eating ice cream!

Turns out I was not alone in my assumption; following the ice cream incident, a large number of ice cream manufacturers changed their approach to environmental pathogen management and the USFDA initiated a full "swabathon" of American ice cream factories.

You may also recall the list of products in my first article and the increasing number of new food groups linked to food poisoning (I have been told that in Australia, rock melons are now classed as a "forbidden fruit" for pregnant women). So, when it comes to food safety, I now remind myself: "I do not know, what I do not know!" (I recently learned this is called: "intellectual humility") For this reason, I recommend an environmental pathogen monitoring routine for all food manufacturing plants. Because, even if you think your product is bullet proof, your food factory should never be allowed to become a pathogen breeding ground

# ENVIRONMENTAL PATHOGEN MANAGEMENT: WHAT ARE WE LOOKING FOR?

When it comes to pathogens, there have always been two categories of food: **low risk or high risk**. Traditionally, this distinction was based on the potential of pathogens to contaminate and, subsequently, grow in the product.

However, an increased number of food poisoning outbreaks have occurred with foods like, fresh and frozen vegetables, ice cream, cereals and peanut butter, which has **challenged our view of “low risk” foods**.

In this third article from our short series on environmental pathogen management in the food industry, Jack van der Sanden suggests that **no factory is truly safe, and that it is important to establish a tailor-made pathogen surveillance program** based on the type of food that is being made.

So, after we have discussed “why?” (article 1) and issued some warning shots (article 2); it's time to start designing our environmental pathogen programme. The first question to ask in the design of any pathogen management programme is: What are we going to look for?

Traditionally, foods have been classified as high or low risk, based on the potential for pathogen contamination and subsequent growth in the product. Typically, fresh products like meat, soft cheeses and shellfish have been classed high risk whereas low pH products like yoghurt, high heat products like UHT and dry products were considered low risk.

Whilst some of the rationale for high and low risk food still stands, the boundary between this “black and white” distinction has become somewhat blurred. For example, following well documented pathogen outbreaks, our views for foods like fresh and frozen vegetables, ice cream, cereals and peanut butter have well and truly shifted. As we improve our diagnostic capability with tools like Whole Genome Sequencing, this list may well continue to grow.

I think it may be more useful to look at food on a grey scale when it comes to pathogens and I now routinely talk about “higher” risk and “lower” risk foods. The reason I raise this point, is that several food factories I have visited do not monitor for environmental pathogens at all, based on the assumption that they produce a “low risk” food. My routine response is that “we don't know what we don't know” (remember?) and at least should be aware of what's lurking in our factory environment.

However, I do agree that an extensive, expensive pathogen management plan for a UHT or yoghurt plant is counterintuitive, so let me introduce the concept of “target” and “background” pathogens.

## Target Pathogens

Listeria monocytogenes in chilled and ready-to-eat products, Salmonella in dry products, Cronobacter sakazakii in infant formula and E. coli in lettuce are all examples of pathogens that are “hard linked” to a specific food group. We know, either through scientific research or from experience that some foods can host/support particular pathogens.

When it comes to the food you make, you are probably very familiar with the pathogen(s) that are a risk to your product and I call these the target or primary pathogens. In a nutshell, “target” pathogens are the pathogens that are known to be a risk to your product and can make your customers sick.

Obviously, if you have a target pathogen associated with the food you make, your environmental pathogen monitoring programme should focus on this pathogen. (If you make food and are unsure if your food category has been implicated and linked to a pathogen, I suggest

you seek some expert advice).

For target pathogens, the purpose of your environmental pathogen programme is to “seek and destroy”! Because left unchecked, this pathogen is a real threat to your food business.

## Background Pathogens

Some food products have never been associated with a known pathogen, nor implicated in food poisoning outbreaks. As a result, the manufacturers of these foods have not been concerned about pathogens in the environment (or their product).

Whilst I understand this reasoning, I'm no longer convinced any food is safe from pathogens. The fact we are now dealing with antibiotic resistant “super bugs”, shows the incredible adaptability of micro-organisms. My thinking is that a heavily contaminated factory environment may well lead to a “house bug” that could start contaminating your product at some point.

I believe in a “safety first” approach; a food plant should never become a breeding ground for pathogens and for this reason I recommend all food plants to have a programme for “background or secondary pathogens”: pathogens that do not pose an immediate risk to your product.

Will we look as hard for background pathogens as for target ones? No! The purpose to monitor for background pathogens is to keep an eye on your factory environment and the focus of the programme shifts from “seek and destroy” to “seek and control”.

In summary, regardless of your product, an environmental pathogen management programme can provide very useful information. In both cases the purpose of “seek” remains but our response will differ.

For higher risk foods, an extensive environmental management programme for target pathogens is strongly recommended, preferably combined with a less frequent routine for the background one. For example, a soft cheese plant may have an extensive programme for Listeria (Target) and a low-level programme for Salmonella (background).

For lower risk foods, a low frequency environmental programme for Salmonella and Listeria will be useful to understand your general factory condition. Because you never know when to expect the unexpected.

— Jack

PS: Sometimes I get asked, why we are not looking for Salmonella and Listeria in equal measure; because they are both dangerous pathogens. However, please consider that, by making no distinction between the two pathogens, every dollar that is spent on a background pathogen will not be spent on finding the real “target” one.

# ENVIRONMENTAL PATHOGEN MANAGEMENT: HOW TO PLAN A PATHOGEN HUNT?

Going on a pathogen hunt without a plan is like **travelling without an itinerary: you'll never know where you end up.**

Without a plan, you take the risk of setting up and paying for an environmental pathogen monitoring program, which may not detect pathogens and give you the illusion that your plant is healthy, when it may be contaminated.

In this fourth article in our short series on pathogen management, Jack van der Sanden introduces a risk-based approach to set up your program; **how to define your sampling points**, their numbers and their frequencies.

"A goal without a plan is just a wish" (Antoine de Saint-Exupery), and this is no different for an environmental pathogen "hunt". The goal of an environmental pathogen programme is to "seek" the target and background pathogens; however, there is no value in swabbing the factory without a clear rationale or plan. If our programme is not designed to find pathogens, it will not be effective, or worse: a lack of pathogen detects may leave us with a false sense of security (like having a smoke alarm with an empty battery).

#### To find a pathogen, you need to think like a pathogen!

All micro-organisms (including pathogens) require three essential conditions to grow and thrive in a factory environment: food – moisture – shelter. Of course, there are other conditions, like oxygen and temperature, which differ between species, however, by controlling food, moisture and shelter in our factory, pathogens will struggle to get established.

Food is minimised by having a clean plant, moisture is controlled by keeping the factory as dry as possible during production and shelter is eliminated by hygienic design and maintenance of our equipment and buildings.

One way to hunt for pathogens, is to walk into the plant and randomly swab the dirtiest spots you can find, targeting the areas where there is food – moisture - shelter (I call this: a worst-case random sampling programme). Whilst this is the preferred approach for traceback sampling, for a routine programme, this method tends to become a logistical nightmare, as we struggle to remember where we swabbed, when we swabbed there last and how to interpret our results.

I once had a client calling me in despair. They kept finding positives in a contaminated area of the plant, where the floors were in poor condition. They were on continuous traceback (and spending an absolute fortune on testing). I suggested that, whilst it was wonderful that they were finding pathogens; maybe, they could change their tactics and "stop sticking their swab in "a turd" to confirm it's still "sh\*t"! Perhaps they could focus their efforts on isolating the area, fixing the floor and swabbing surrounding areas to monitor whether the contamination was spreading?

The moral of this story is that if we have a fully random programme targeting the worst-case areas, chances are we may end up chasing our tail.

We need a more structured plant monitoring programme, starting with the premise that the plant is clean (with no food – moisture – shelter), because going pathogen hunting in a dirty plant is a bit like "shooting fish in a barrel".

To design this programme, I have used risk management principles.

#### The Pathogen Risk Matrix

Most International guidelines on Salmonella and Listeria are based on proximity: the closer you are to the product the higher the risk for product contamination. Generally, four proximity categories are included: product contact surface, close, further and far. However, defining the difference between close, further and far has been difficult to say the least.

To deal with this issue, I suggest three proximity categories: close (the outside of process equipment), far (floors, walls, drains) and in-between (stuff that moves between far and close). Please note that to me, product contact surface swabbing for pathogens is the same as final product testing, because a positive

result for a product contact surface swab during manufacture, means our product is contaminated (we have moved from the smoke into the fire).

Something, which is not covered in the international guidelines, is the actual food process itself. Clearly, it is not possible for generic pathogen guidelines to cover all the different food processes, however, I believe it is really important to ask two very relevant process questions for pathogen management:

1. Does our process have a validated kill step?
2. Is our product enclosed or exposed to the factory environment following this kill step?

If we have a validated pathogen kill step in our process, we can expect to find pathogens before this kill step (otherwise why have a kill step?). Therefore, swabbing extensively before a kill step will only confirm what we already know.

If our product is exposed following the kill step, the risk of environmental re-contamination of our product is high, and we should definitely focus our pathogen hunt in this "post-contamination zone" of our factory.

When it comes to pathogens in the environment, the risk to the product increases depending how close we are to the product and where we are in our food process.

If we combine proximity and process, and consider proximity as likelihood and process as impact, we end up with something most people may recognise – a risk matrix, which shows: **the pathogen contamination risk to our product.**

#### 3P MODEL

PROXIMITY/LIKELIHOOD	Close (zone 2)	MEDIUM	HIGH	HIGH
	In-between (zone 3)	LOW	MEDIUM	HIGH
	Far (zone 4)	LOW	LOW	MEDIUM
		STANDARD	CONTROLLED	HIGH CARE
		PLANT HYGIENE ZONE/IMPACT		

This risk-based approach gives us a logical starting point and guides our environmental pathogen monitoring efforts. The colours can be used to establish our sampling numbers and frequencies (more in red/less in green), but more importantly, they can guide our response in case of a pathogen detection. (to be discussed in the next article).

Unfortunately, whilst the matrix will point us in the right direction and ensures our programme targets the right areas, it does not tell us, how to pick our sample points. This activity requires an initial plant risk assessment, which should include a review of traffic flows, people movement and process access points.

To complete this risk assessment, I recommend using expert input (independent from the factory), because when it comes to going on a pathogen hunt, nothing beats a fresh pair of experienced eyes.

# ENVIRONMENTAL PATHOGEN MANAGEMENT: SURPRISE, WE FOUND A PATHOGEN!

This is the last chapter of our short series on environmental pathogen management. The previous articles will have given you some insights for an environmental pathogen management program in your factory.

There is only one point left that has not been addressed: **what to do if you find a pathogen in your plant.** Panic is often the first reaction, but **it shouldn't be if you have a predetermined response plan.**

Jack van der Sanden, in this fifth and final article, explains what to do when one of your pathogen samples comes back positive and highlights some actions to mitigate the impact.

So, we have designed our pathogen program, conducted a risk assessment to determine our swabbing points, found an accredited laboratory and kicked-off the monitoring – PHEW - peace of mind! That is of course, until that phone call on a Friday afternoon, telling us that one of our environmental swabs has come back positive (It's always a Friday afternoon!).

The most common reaction I have seen is: panic! A mad last-minute crisis meeting and some poor souls spending their weekend in the factory, running around cleaning and swabbing. I vividly remember my first Listeria hunt about 20 years ago (during the weekend!), as we were joint by a very senior (and somewhat grumpy) manager to guide us and keep an eye on proceedings.

### It doesn't have to be this way!!!

A good environmental pathogen management program should include a documented pre-determined response plan. Remember the reason we started our hunt for that pathogen? It was to find that pathogen in the environment, well before it sneaked its way into our product. So, we shouldn't be surprised if we get a positive result, instead we should congratulate ourselves: Yippee, our monitoring program is working!

Fortunately, we can use the colours in the risk matrix from my previous article to guide our response plans. Because, in my view, a response to red, orange or green needs to be different. However, before we start writing down our actions for each colour, I would like to introduce "risk appetite".

I'm not sure if you have ever spoken to a financial advisor? One of the first things they do, before they start talking investment options, is to gauge your risk appetite; whether you are risk averse or whether you are prepared to take the occasional loss on your journey towards financial freedom.

When it comes to our pathogen risk matrix, this is no different. I have sat in meetings where the different risk appetites of the various parties caused some real friction. Therefore, the first step is to determine the risk, acceptable to the business, the regulator and the auditors. Once we have agreed on our stakeholders risk appetite, we can lock in our pre-determined response for each colour.

For example, I'm a food safety professional and conservative when it comes to pathogens, so here's my preferred response plan for a target pathogen:

**Green: Expected** – some traceback swabbing to determine the size of the problem (and maybe find the cause).

**Orange: Surprise** – more rigorous traceback swabbing and increased final product sampling and testing moving forward.

**Red: Scary** – intensive traceback swabbing and additional final product sampling before release from the date of the last clear result (if possible, because your product needs to be in your control).

(Note that we are talking target pathogen. For the background pathogens, only a traceback is recommended).

To do a traceback, the worst-case random swabbing technique (previous blog) is now appropriate, because we know the pathogen somewhere and we want to find the source.

This is not easy; in a large number of cases, you will struggle finding the pathogen again (only for it to pop up a few months later!). I think the main reason for this lack of success, is a response that is poorly co-ordinated and too fast. Evidence to date shows that one of the biggest advantages of an environmental pathogen management programme is: we have time to do a proper job! (remember Company X in my first article?)

For this reason, I'm somewhat concerned about the latest "instant" or "very rapid" testing technology for pathogens. Whilst I can see the benefits for FMCG manufacture and traceback investigations, an environmental pathogen test should never become a line clearance tool like ATP, because pathogens should by definition "not be" in your factory and a positive result must always lead to a full investigation.

I would also like to reiterate my warning about "false" results. Ideally, we should use the same accredited test method for all our pathogen testing (environmental as well as final product) to prevent any test method debates (and believe me, they do happen when it comes to a positive pathogen result).

A positive environmental pathogen result is a time to reflect instead of panic (what's going on!?). We need time to maximise our chances finding the cause, so we can improve our controls and systems. As I once said to the CEO of a large multinational food company: "I'm not concerned if we find a pathogen in one of the factories, but I do get concerned if the response to that find is lacking."

So, here are some response plan tips:

- Grab your (pre-prepared) response checklist.
- Bring in some fresh eyes (the hunt is on!)
- Conduct an environmental housekeeping inspection first (identify the "food – moisture – shelter" spots)
- Review factory manufacturing records for unusual events/changes
- Observe factory traffic movements for breaches
- Include vector swabbing (has it spread? Where has it come from?)
- Do your traceback swabbing before your deep clean.
- Consider swabbing for hygiene indicators (EB, Coliform) as well
- Consider swabbing over several days

And the list goes on!

I hope you have enjoyed this mini-series and I have shown, that an effective environmental pathogen program is more than a "swab here and there".

We have explored why we should have an environmental pathogen program, what pathogens to look for, how to look for them and what to do if we find them. I have also shared some personal lessons and experiences with you, because pathogen testing can be very costly to your food business – if you get it wrong.

Finally, if it all feels a bit overwhelming, please connect; I'm more than happy to support your journey towards a robust pathogen program, so you can have a good night's sleep!

Thanks for reading!